

# EXECUTIVE COMMITTEE MEETING SUMMARY

Las Vegas, Nevada June 1-2, 2006

Thursday, June 1, 2006

## **Welcome and Introductions**

Dr. James H. Johnson, Jr. (Howard University), Chair of the Board of Scientific Counselors (BOSC), was unable to attend the meeting so the Vice-Chair of the BOSC, Dr. Rogene Henderson (Lovelace Respiratory Research Institute) chaired the meeting. She called the 32nd face-to-face meeting of the BOSC Executive Committee to order at 8:30 a.m. She thanked the members for coming and offered a special welcome to the new Board members present, Dr. Ken Demerjian (State University of New York) and Dr. Barry Ryan (Emory University). Dr. Demerjian is the Director of the Atmospheric Sciences Research Center at the State University of New York and he served on the BOSC Subcommittee that reviewed the Particulate Matter (PM)/Ozone Research Program. Dr. Ryan is in the Department of Environmental and Occupational Health of the Rollins School of Public Health at Emory University. His expertise is exposure assessment and environmental chemistry. Dr. Henderson asked the members and other attendees to introduce themselves. Following the introductions, she explained that two additional new members, Dr. Martin Philbert (University of Michigan) and Dr. Carol Weiss (Harvard University) were unable to attend the meeting. The biosketches of the four new BOSC members were included in the meeting notebook.

Dr. Henderson circulated an article from *C&E News* that highlighted Dr. George Gray, the Assistant Administrator for Research and Development (AA/ORD), and the changes expected for research at EPA.

#### **Approval of the February 2006 Meeting Minutes**

Dr. Henderson asked if there were any comments on the draft summary of the February 13-14, 2006 BOSC Executive Committee meeting. No comments were provided so Dr. Henderson called for a motion to approve the minutes. Dr. Herb Windom (Skidaway Institute of Oceanography) made a motion to approve the minutes and Dr. Jim Clark (Exxon Mobile) seconded the motion. The February minutes were approved unanimously by the BOSC.

## **Review of April 2006 Conference Call Minutes**

Dr. Henderson asked for comments on the draft summary of the April 6, 2006 BOSC Executive Committee conference call. Dr. Windom indicated that the summary was very helpful in finalizing the report. No additional comments were provided so Dr. Henderson called for a motion to approve the summary. Dr. Anna Harding (Oregon State University) moved to approve the April conference call summary, and Dr. Windom seconded the motion. The April conference call summary was approved unanimously by the BOSC.

## **BOSC Reports Transmitted to ORD**

Dr. Henderson stated that a number of BOSC reports have been transmitted to ORD, including the Risk Assessment Workshop Letter Report, the ORD Management Multi-Year Plan (MYP) Letter Report, and the Global Change Program Review Report. The vettors assigned to review these reports verified that the final changes requested by the BOSC Executive Committee had been made before the Chair transmitted them to ORD. Dr. Henderson mentioned that the Land Restoration and Preservation Program Review Report, which was reviewed and approved by the Executive Committee, has been finalized but changes must be verified by the BOSC vettor before it is transmitted to ORD.

Dr. Henderson reported that both she and Dr. Johnson attended the Science Advisory Board (SAB) budget review meeting. There were several very positive comments about the BOSC at that meeting. She noted that the program reviews conducted by the BOSC are well regarded by the SAB and the Agency.

## Overview of the Agenda

Dr. Henderson reviewed the agenda for the 1 ½ day meeting. The first day included administrative remarks by the Designated Federal Officer (DFO), the Subcommittee and workgroup reports, a presentation of BOSC issues and the ORD update, ORD responses to recent BOSC reports, a discussion of the BOSC Subcommittee Chair Handbook, an update on implementing the standing BOSC laboratory/center subcommittees, a presentation on Project Horizon, and a report on SAB activities. The agenda for the second day included a site visit to the National Exposure Research Laboratory (NERL) facilities and a discussion of future BOSC business. Dr. Henderson asked if there were any additions or changes to the agenda, and none were suggested.

## **BOSC DFO Remarks**

Ms. Lorelei Kowalski (EPA/ORD), Designated Federal Officer (DFO) for the BOSC Executive Committee, stated that the BOSC is chartered as a Federal Advisory Committee and subject to the rules and regulations of the Federal Advisory Committee Act (FACA). Therefore, this meeting was open to the public, and time was designated for public comment. A contractor, Beverly Campbell from SCG, was present to take notes to capture the presentations and discussions, and the meeting minutes will be made available to the public on the BOSC Web Site after approval by the Executive Committee and certification by the acting BOSC Chair, Dr. Henderson. Notice of this meeting was published in the Federal Register. Ms. Kowalski established an electronic public docket for the meeting on the Federal Docket Management System (FDMS), which can be accessed at http://www.regulations.gov. The number to search for this docket is EPA-HQ-ORD-2006-0423. The Federal Register notice and the agenda are available on the docket. Ms. Kowalski mentioned that she had not received any requests for public comment prior to the meeting but there is time set aside at 4:00 p.m. today for public comment. She noted that there was one request for the call-in number. As DFO, she worked with EPA's ethics officials to ensure that all appropriate ethics requirements were satisfied for the Executive Committee. Nevertheless, she asked the members to notify her during the meeting if they have any potential conflicts of interest. Each BOSC member should have received a notebook of materials by mail prior to the meeting as well as some additional handouts upon check-in to the hotel. Dr. George Gray and several of the other presenters will be joining the meeting by telephone on Thursday.

Friday's meeting will be held at the NERL facility. She asked the Board members to meet in the lobby between 7:30 and 8:00 a.m. for transportation to NERL. The discussion of future business will be held at the laboratory so those with early flights should plan to leave from there to go to the airport. The site visit will include an overview of the laboratory and two presentations on specific research topics.

Ms. Kowalski introduced Susan Peterson (EPA/ORD), who will be serving as the DFO for three of the new standing subcommittees for the ORD laboratories/centers. Heather Drumm (EPA/ORD) will be

returning from maternity leave in July and she will serve as the DFO for the Safe Pesticides/Safe Products Subcommittee and one of the standing laboratory/center subcommittees. Ms. Kowalski also will serve as the DFO for one of the standing laboratory/center subcommittees.

The current payroll system used by EPA, Employee Express, is being replaced. Ms. Kowalski has been meeting with EPA staff members who support the various FACAs to discuss potential problems that may arise and ways to prevent them. The new payroll system was implemented on Sunday, May 28, 2006. This new system services about 800,000 federal employees and is managed outside of EPA. Employees can access their earnings and leave statements through the new system (i.e., My Pay). Ms. Kowalski will be receiving a login and PIN number for each BOSC member. (Note: If a BOSC member also serves on the SAB, he/she will use the same login and PIN number for both Boards.) Ms. Kowalski will send each member his/her login and PIN number once she receives them. She asked the Board members to log onto the system and verify that their information is correct. She noted that no historical payroll information will be posted until after the BOSC members have been paid following the June meeting. Members can access the system to change their number of exemptions, address, marital status, etc., and to print earnings and leave statements. Members also can view and print their W-2 forms (there will be a separate W-2 for each FACA committee). BOSC members can request an e-mail alert to notify them when earnings and leave statements are available on the system. If desired, a BOSC member can give permission to Ms. Kowalski to access his/her information so that she can make the desired changes; however, she thought it would be more efficient for members to manage the information themselves. She noted that My Pay keeps only 1 year of records, so if members want long-term records, they should print out statements periodically. Dr. Demerjian asked if the members would continue to receive direct deposits if they were getting them through the old system. Ms. Kowalski replied that she thought so, but she agreed to verify this. She pointed out that this is a new system and despite the fact that EPA has tried to anticipate and prevent problems, there certainly will be some issues that need to be worked out. The Web address for My Pay is http://www.mypay.gov. Ms. Kowalski will be sending everyone a follow-up e-mail about how to access the new system. She asked the Board members to send her any questions they might have about the system and she will provide them the answers.

Ms. Kowalski will be collecting timesheets for the hours worked to prepare for this meeting and she will add the hours for the meeting. Dr. Henderson pointed out that there was a timesheet included in the meeting notebook. Ms. Kowalski reminded the BOSC members that she needs receipts for all expenses that exceed \$75, which typically is the hotel receipt. A list of smaller expenses can be submitted to her by e-mail. She asked any attendees who had not done so already to sign in at the registration desk.

## Remarks of the AA/ORD

Dr. George Gray, who joined the meeting by telephone, thanked the BOSC members for their efforts to strengthen Agency science and welcomed the new members to the Board. He expressed his hope that the new members will find the efforts of the BOSC stimulating as they discover the breadth of ORD activities and the passion of the ORD staff.

He recently received a number of reports from the BOSC, including the Global Change Research Program Review Report. He is gratified by the many compliments in the report and he appreciates the helpful recommendations. He was intrigued by the suggestion to integrate Global Change Research across various research programs. That is exactly the type of broad thinking needed from these reviews. He thanked the BOSC for considering the implementation of standing subcommittees for the laboratories/centers. Dr. Bob Kavlock, Director of the National Center for Computational Toxicology (NCCT), has found the advice provided by the Computational Toxicology Subcommittee, the only current standing BOSC subcommittee, to be very helpful. The Subcommittee has provided feedback on the Center's research plan and now will be reviewing the research being conducted by the Center.

Dr. Gray expressed his hope that the Board members enjoy their tour of the NERL-Las Vegas laboratory. He has toured a number of the ORD laboratories/centers and these visits have helped him develop a better understanding of what ORD is doing and the importance of that work.

Dr. Henderson asked if there were any questions for Dr. Gray. No questions were posed, so Dr. Henderson thanked Dr. Gray for his comments.

#### **Subcommittee Reports**

Computational Toxicology Subcommittee

Because Dr. George Daston (Proctor & Gamble), Chair of the Computational Toxicology Subcommittee, was unable to attend the meeting, Dr. Clark, who serves on the Subcommittee, provided the Subcommittee report. Dr. Clark reminded the BOSC members that the NCCT was created about 2 years ago by pulling together resources from within ORD. The BOSC formed the Subcommittee to provide advice to the Director as the Center was established and expanded. The initial members of the Subcommittee included Drs. Daston, Clark, and Clegg as well as Dr. Richard Di Giulio from Duke University. The Subcommittee met face-to-face in Research Triangle Park, North Carolina, in April 2005. The Subcommittee prepared a letter report following that meeting. It became clear that additional expertise was needed to advise the Center so the Subcommittee was expanded to include two additional members: Dr. M. Moiz Mumtaz from the Agency for Toxic Substances and Disease Registry and Dr. John Quackenbush from the Dana-Farber Cancer Institute.

The next Subcommittee meeting will be held June 19-20, 2006, in Research Triangle Park, NC. The focus of this meeting will be a review of the implementation plan, the two bioinformatics centers, and a number of research projects. There also will be several posters presented at the meeting. Dr. Clark noted that the NCCT is a virtual center that relies on expertise from across various ORD laboratories and centers as well as the Science To Achieve Results (STAR) Program.

## STAR/GRO Fellowship Subcommittee

Because Dr. Henderson was one of the vettors of this report, she asked Dr. Harding to serve as the Chair for the discussion of the STAR/GRO Fellowship Subcommittee report.

Dr. Clifford Duke (The Ecological Society of America), Chair of the STAR/GRO Fellowship Subcommittee, presented the STAR/GRO Fellowship Program Review Report to the Executive Committee. The STAR Graduate Fellowship Program was initiated in 1995, and it has been funded at about \$10 million/year, awarding approximately 100 fellowships annually. The GRO Undergraduate and Graduate Fellowship Programs were derived from Culturally Diverse Academic Fellowship and Minority Academic Institution (MAI) Programs dating back to 1981. The budget for the GRO Undergraduate Fellowship Program is approximately \$650K/year and it awards 15 fellowships each year. The GRO Graduate Fellowship Program has annual funding of approximately \$1.5 million and it awards about 15-20 fellowships each year. In 2003, the eligibility criterion for the GRO Fellowship Programs was changed from MAIs to institutions that receive less than \$50 million of federal R&D funding per year. That level was subsequently reduced to \$35 million of federal R&D funding per year.

The charge of the STAR/GRO Fellowship Subcommittee focused on the: (1) achievement of desired program outcomes; (2) fellowship recipient selection process; (3) utility of research for decision-making and policy; (4) practices, resources, and effectiveness of outreach for diversity; and (5) resources, information management, and communication processes and procedures.

The Subcommittee found that the STAR/GRO Fellows have made excellent contributions to their fields of study. The fellowship programs are of value to EPA and the nation, and to the Fellows themselves.

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The Subcommittee also found that the programs would benefit from improved information collection and evaluation. Because the GRO Fellowship Programs lack sufficient resources to achieve the stated purpose of building capacity for environmental research at under-funded institutions, the Subcommittee recommended that EPA consider a major restructuring of the programs, possibly eliminating the GRO Fellowship Programs as they currently exist. ORD should consider improving the marketing of the STAR Fellowship Program to minority-serving institutions and creating regional consortia designed to focus on environmental science opportunities for undergraduates. The Subcommittee believes that the consortia approach would be a more effective use of the existing resources to achieve the goal of building capacity.

The other findings and recommendations of the Subcommittee include:

- ♦ Consider increasing the funding for the STAR Fellowship Program and specifically an increase in the expense budget for individual fellowships.
- → Expand the mentoring effort of the STAR Fellowship Program. The Subcommittee members believe that the GRO graduates could compete successfully for STAR Fellowships.
- ♦ Review the impacts of the 2003 eligibility criterion determination for the GRO Fellowship Programs. A number of non-minority institutions currently are receiving GRO Fellowships. Perhaps EPA should seek legislative authority to reinstitute the original eligibility criterion.
- → Explore potential augmentation of the GRO Fellowship Program funding with the Experimental Program to Stimulate Competitive Research (EPSCoR) funds.
- ♦ Update the descriptions of criteria in funding announcements for fellowships. For example, the announcements do not indicate that the peer review is followed by a relevancy review. This should be specifically stated in the Requests for Applications (RFAs).
- ❖ Consider potential changes in the process for Masters versus Ph.D. applicants. Some Subcommittee members thought the Masters Fellows should be eliminated from the pool but others thought that the Masters should be allowed to compete for the fellowships. It was suggested that EPA use separate review panels for Masters and Ph.D. applicants.
- ♦ There were insufficient data available to address the utility of the research. Therefore, the Subcommittee did not evaluate the usefulness of the research.
- ♦ ORD needs to improve information collection for the Fellows (e.g., publication records, resume updates, general tracking of Fellows) to provide data for evaluating the utility of the program.
- ♦ Awareness of the fellowship programs is widespread as evidenced by the large, qualified pool of applicants for the STAR Fellowship Program.
- ♦ The ability to evaluate the fellowship programs would benefit from improved data collection.
- ♦ Additional funding would help maintain the value of the fellowships against inflation.
- ❖ Information management is a general concern. EPA needs to do more to track former Fellows, possibly requiring them to submit an update every 5 years for 10 years following receipt of the fellowship. EPA should use tools to track the publications of former Fellows.
- ♦ Communications with minority institutions, communities, and Congress could be strengthened.

Dr. Duke thanked the Subcommittee members for the excellent work that they did in a short timeframe. He also thanked the EPA staff for providing the information needed to conduct the review.

Dr. Harding asked the two vettors, Drs. Henderson and Windom to provide their comments on the report. She noted that editorial changes could be submitted to Dr. Duke that did not require discussion; substantive comments/changes, however, must be discussed.

Dr. Windom commented that there was little mention of gender diversity in the report. Is that a consideration in the selection process? Dr. Duke replied that gender diversity was not specifically mentioned by the EPA staff or the Subcommittee members. He did not know if EPA used it as a criterion in the selection process. Dr. Farland stated that EPA's approach has been to select the best qualified candidates. The Agency is limited by how much it can consider minority and gender in the selection process. Dr. Windom mentioned this because one of EPA's goals is to increase the cultural and gender diversity of its workforce and the fellowships are a means to feed the workforce pipeline. Dr. George Lambert (University of Medicine and Dentistry of New Jersey) asked about the present percentage of minorities and women in technical positions at EPA. Dr. Farland responded that the Agency is doing much better with gender, but needs more improvement in the area of minorities.

Dr. Windom continued with his comments on the report. There is no clear assessment of outcomes. The fellowship programs have focused on process and not outcomes, which are very important for continued funding. The Agency should figure out what it is trying to achieve with the fellowship programs. Dr. Windom thought the report should include a recommendation that EPA specify expected outcomes (e.g., diversity among the future environmental scientists). He also thought the structure of the report could be improved. There was a considerable amount of redundancy in the report. For example, the section on funding level is repeated about six times in the report because of its current structure. Dr. Windom suggested restructuring the report to eliminate the redundancy. This also would shorten the report.

Dr. Windom expressed some concern about the recommendations that did not represent a consensus of the Subcommittee. For example, the recommendation about eliminating Masters applicants did not represent the consensus of the group. Such issues need to be resolved. He did not see a strong argument for separate review panels for the Masters and Ph.D. applicants; he assumed that in most cases the reviewers will probably give more weight to the Ph.D. applicants.

Dr. Duke said that many of Dr. Windom's remarks were similar to those brought up in the discussions of the Subcommittee members. He acknowledged that there was no consensus about eliminating Masters applicants or the use of separate review panels. How should the non-consensus viewpoints be handled in the report? He did not want to delete them from the report because he thinks it is useful for EPA to receive these comments. Dr. Clark agreed that these non-consensus comments should be provided to EPA; however, non-consensus comments should not reach the level of findings and recommendations in the report. They should be included only in the discussion section. Dr. Windom agreed with Dr. Clark's assessment.

Dr. Windom approved of the idea of creating regional consortia. Through the consortia, minority institutions can partner with more experienced institutions to provide the students the opportunity for research experience. Both the National Oceanic and Atmospheric Administration (NOAA) and the National Science Foundation (NSF) do this successfully. He believes that the report dilutes this recommendation by including alternative recommendations to implement if EPA decides not to implement the consortia suggestion. Dr. Duke responded that the Subcommittee wanted to include recommendations that could be implemented in the short-term to improve the programs. The rationale was that it will take some time to restructure the program into regional consortia and there are steps that EPA can take in the interim to improve the existing programs.

Dr. Henderson agreed that there was redundancy in the report but she was not bothered by it. She thought the recommendations in the report were clear and easily understood. The report does a good job of

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pointing out the weaknesses of the current programs. Although she liked the idea of regional consortia, she wanted some explanation of how it would work. An example might be helpful.

Some of the recommendations mentioned in the report text were not included in the summary. For example there is a sentence in the report about eliminating the Fellowship Information Inventory (FII) because it was not designed to meet the Agency's information collection needs, but that recommendation is not in the summary. Dr. Duke replied that such recommendations may have been overlooked. He thought all of them were included in the summary.

The report suggests several options for increasing GRO Fellowship funding. One of those was to take funding from the STAR Fellowship Program to fund the GRO Fellowship Programs. Dr. Henderson did not think that the BOSC should make this recommendation. She also asked if it was common for graduate students to maintain Web sites. Dr. Duke replied that although many students do not have Web sites, they usually develop them once they enter academia. Many former Fellows probably maintain Web sites and post their publications on the sites.

Dr. Henderson was not sure she agreed that the GRO Fellowships should be limited to minority institutions. She mentioned that many minority institutions receive funding to build facilities but they do not receive the funding to staff them or maintain the equipment. She cautioned that the Agency needs to be aware of how the money is being used. Dr. Windom agreed, stating that the consortia concept would be more effective in achieving the goal of capacity building. Dr. Gary Sayler (University of Tennessee) asked about the motivation for universities to form these consortia when there are so few resources available from EPA. Dr. Windom responded that the motivation of the universities would be to bring minority students into their research projects. Collaboration with minority students would benefit the universities' programs and provide the minority students access to experienced mentors.

EPA funds only 15-20 GRO Fellowships each year. Dr. Farland asked the BSOC what number of Fellows per consortia would be acceptable. If that number is five students, then EPA could fund three consortia. One finding that stood out to Dr. Farland was the large number of institutions that had a single student supported by this program. He agreed that this was an inefficient use of resources.

Dr. Windom commented that if EPA develops an RFA for regional consortia and identifies outcomes, he thinks there will be groups that logically fit together to build capacity and they will compete for the awards. This approach has worked very well to increase the number of minority students studying marine sciences. Dr. Henderson asked if EPA was prohibited from limiting GRO Fellowship funding to minorities. Dr. Farland responded that he did not know if EPA had any flexibility on this issue because it is based on a Presidential directive on how support can be provided to individuals. EPA has been interested in helping to fund minority students through a Society of Toxicology program, but the Agency was prohibited from doing so because of this directive.

Dr. Clark reiterated his earlier comment that the non-consensus recommendations should not be included in the list of findings and recommendations because to do so would give too much weight to minority opinions. They should be mentioned only in the discussion. He also thinks the Subcommittee may be overstepping its bounds by recommending that the information tracking system be maintained by EPA rather than a contractor. That is too prescriptive. The Subcommittee should just make suggestions on what such a system should track. Dr. Clark noted that it is difficult to track the careers of former Fellows. He suggested maintaining contacts with the institutions' alumni associations to obtain information on former Fellows. Dr. Windom agreed that it will be very difficult to rely on the former Fellows to provide the information. He suggested conducting searches of sources such as Google Scholar to obtain information on former Fellows. Dr. Duke said that the former Fellows present at the face-to-face meeting were very enthusiastic about the program and they probably would be willing to provide information to EPA about their careers. Dr. Harding said that accredited institutions attempt to track alumni and have difficulty doing it. She thinks the Subcommittee suggestion of withholding future funding from institutions if former Fellows do not provide the information may be too strong. Dr. Windom pointed out

that it is in EPA's interest to collect this information; therefore, the Agency needs to put some effort into this. He recommended that EPA conduct telephone surveys to obtain information from former Fellows. Dr. Sayler commented that fellowship applications are associated with faculty members; perhaps these faculty members can provide useful information. Dr. Duke stated that a number of Fellows cited interaction with EPA staff as an advantage so the Subcommittee recommended that the mentoring component of the program be formalized. If that relationship is more formal, perhaps these mentors can keep track of the Fellows' careers.

Dr. Sayler asked how many more institutions were brought into the pool of eligible institutions when the eligibility criterion changed from \$50 million to \$35 million. Dr. Farland replied that the \$50 million threshold allowed some larger institutions that had few minorities to compete for GRO Fellowships. Therefore, EPA decided to lower the funding level. Dr. Sayler asked about geographical distribution. Is this taken into consideration in the selection process? Dr. Windom commented that the report states that EPA uses geographic diversity to eliminate applicants because only 100 of 200 applications that received a rating of excellent are funded. He thought Dr. Duke's suggestion of the EPA mentors following the former Fellows' careers was a good one. The mentor could receive a copy of the Fellow's thesis and ensure that the research results were captured by EPA. Dr. Henderson agreed that an EPA mentor may help with the tracking problem; she also thought summer internships at EPA facilities would be helpful. Dr. Sayler pointed out that, given ORD's limited funding for the fellowship programs, a regional consortia approach would only lead to geographic narrowing because only three consortia could be funded each year. Dr. Windom said that EPA could fund the consortia that will lead to early success. The impact will be that the minority students who receive their Ph.D. degree will take jobs at minority institutions across the country, building the capacity at these institutions. If building capacity is the goal rather than geographic diversity, then the consortia approach will be more effective. Dr. Henderson pointed out that the geographic diversity in the existing program is not very good.

Dr. Farland asked Stephanie Willett (EPA/ORD/NCER), who joined the meeting by telephone, to comment on the mentoring requirement of the GRO Fellowship Programs. Ms. Willett replied that there is a mentoring requirement only for the GRO undergraduate Fellows. The internship is between the junior and senior years of college. The students do the internship at one of the EPA laboratories/centers or EPA headquarters. The extent to which that internship guides the Fellows' research and their careers varies among the EPA Project Officers. Some of the Project Officers are scientists but some are not. Therefore, the mentoring role has been informal and *ad hoc*.

Dr. Ryan said that he thought the low success rate for applicants would discourage students from getting advanced degrees in an environmental field (only 100 of 1600 applicants were funded). Given the large number of applicants, it appears that there is an adequate number of students seeking Ph.D.'s in environmental fields. What is EPA trying to achieve? Dr. Demerjian asked if the numbers Dr. Ryan quoted included both STAR and GRO Fellows. Dr. Duke responded that those numbers included only the STAR Fellowships. STAR applications are reviewed by peer review panels and then EPA does a relevancy review of those rated excellent to select the ones to award. He noted that the statistics for the GRO Fellowships are not included in the report even though EPA supplied those numbers to the Subcommittee. Dr. Demerjian asked if the success rate for GRO was similar to that for STAR. Dr. Duke replied that the success rate for the GRO Fellowship Programs is about 33 percent, compared to the 6 percent for the STAR Fellowship Program. Dr. Duke added that the ratio of applications to funded Fellows is lower for GRO than for STAR. Dr. Demerjian asked if all of the GRO applications awarded were rated excellent, and Dr. Duke responded that some of the applications were rated very good. Dr. Ryan commented that it is clear that there is a large number of students seeking advanced degrees in environmental science. Therefore, the Agency should consider focusing its efforts on building capacity at minority institutions.

Dr. John Giesy (Michigan State University) stated that he objected to the redundancy in the report. He found it annoying and thought Dr. Gray would as well. He also took exception to the wording "minority-serving" institution. All institutions serve minorities. Dr. Duke responded that "minority-serving" is a

term of art. Dr. Giesy expressed his dissatisfaction with the fellowship programs. He resented spending time reviewing excellent proposals that are not awarded because of lack of funds. Perhaps EPA would do better by investing the money in the laboratories/centers and allowing them to partner with minority institutions. The current program has many problems, including the lack of mentoring and critical mass. Dr. Lambert commented that if the Subcommittee members think the fellowship programs are important, the report should state that clearly, because the funding for the fellowship programs is on the "chopping block" each year. He agreed that only funding 1 in 16 applications is not very encouraging. Is there a gender and minority diversity problem at EPA?

Dr. Windom countered Dr. Giesy's comments by stating that he thought the fellowship programs were beneficial to EPA because they fund a number of non-traditional research studies by graduate students who have some unusual, novel ideas. Some of these applications are very impressive and they clearly do not fit into the traditional research programs at most institutions and it would be difficult to justify funding them within the context of traditional programs.

Dr. Demerjian said that he did not think Masters applicants should be excluded. He also did not think they should have separate review panels for Ph.D. and Masters applicants. That would create potential inequities in the process. He posed several questions: How many pipeline programs are there for training minority scientists? Is that part of the capacity building effort? Is the goal to build capacity at institutions or is it to ensure a steady pipeline of well-trained minority scientists? How would the elimination of the GRO Fellowship Programs affect that pipeline? Can minority students effectively compete for STAR Fellowships? Dr. Duke replied that the Subcommittee members thought the GRO graduate applicants could effectively compete for STAR Fellowships. Dr. Farland said that Dr. Demerjian raised some good questions about what EPA is trying to accomplish. The STAR Fellowship Program was designed to bring additional scientists into the environmental field. He noted that many of the Agency's post-docs did not realize that EPA had laboratories and did research before coming to the Agency. EPA wants to communicate to the students that the Agency conducts research and identifies research needs. Although many of the Masters Fellows may pursue an environmental profession rather than research, there is added value when these future environmental professionals have a research background.

Dr. Duke agreed with Dr. Clark's suggestion that the minority opinions should not be included in the findings and recommendations of the report, but will remain in the discussion. Dr. Giesy said that one major problem is that the goals of the fellowship programs are not well articulated. Once the goals are articulated, the Agency should determine if the existing programs are the most efficient way to meet these goals. He suggested that the BOSC discuss this in more detail and help the Agency figure out a way to use the resources available to efficiently accomplish the stated goals. Dr. Giesy also thought the report should be better organized. Dr. Harding asked the Board members to summarize their comments and provide them to Beverly Campbell. SCG will compile the comments and distribute them to the members. The items will be discussed tomorrow if time allows or on a subsequent conference call if the issues cannot be resolved or if the members are not ready to vote on approving the report. Ms. Kowalski said that the purpose of this discussion is to come to resolution on these issues; however, if the issues cannot be resolved during the meeting, she will schedule a conference call in 4 to 6 weeks.

In the interest of time, Dr. Henderson moved on to the other Subcommittee reports. Ms. Kowalski pointed out that there are draft charge questions for a number of the Subcommittees. There is one for the Computational Toxicology Subcommittee in the binder (under the Subcommittee Reports tab following the STAR/GRO Fellowship Report), and draft charges for the Human Health Risk Assessment Program Review, Safe Pesticides/Safe Products Program Review, and the Standing Laboratory/Center Subcommittees were distributed in the packet received at check-in. Dr. Demerjian asked who develops the charges. Ms. Kowalski responded that an initial draft of the charge is prepared by EPA. It is provided to the Subcommittee Chair for input and then provided to the Subcommittee members for their input. This back and forth process continues until the charge is finalized. She noted that the draft charges are not always submitted to the Executive Committee for comment; however, at the February meeting, Dr. Johnson identified a list of items to be included in every charge. He wanted the Executive Committee to

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have an opportunity to review these draft charges to ensure that those items have been incorporated. Dr. Farland commented that the Executive Committee is trying to standardize the charge for the program reviews. He is not certain that this will apply to the standing subcommittees. Dr. Demerjian asked if the BOSC plays a role in identifying anticipatory issues. Dr. Henderson responded that they have been included in the program reviews. Ms. Kowalski said that even though the Executive Committee has agreed on a set of standard questions for the program reviews, the charge questions can be expanded and tailored to the specific Subcommittee review.

Dr. Clark said that the charge for the Computational Toxicology Subcommittee reflects the discussions that the Subcommittee has had with the NCCT management with respect to the types of advice needed by the Center. He noted that the charge questions differ from those for the program reviews. Ms. Kowalski stated that the charge to the Computational Toxicology Subcommittee is being provided to the Executive Committee because it is the only existing standing subcommittee of the BOSC. Dr. Henderson pointed out that the charge is very specific to the Center. Dr. Clark commented that the generic charge for the standing subcommittees for the laboratories/centers should identify areas to be tracked by the Subcommittee rather than a list of charge questions.

#### Technology for Sustainability Subcommittee

Dr. Giesy reported that he sent a list of the areas of expertise required for the Technology for Sustainability Subcommittee to Ms. Kowalski. He also submitted a list of names for consideration. Ms. Kowalski indicated that the formation of the Subcommittee is proceeding slowly. The areas of required expertise have been identified and a list of candidates has been prepared. That list has not been provided to Dr. Giesy because the Subcommittee charge has not been developed. Dr. Farland commented that EPA provided briefings to the Executive Committee on the Sustainability Research Program and the MYP on Technology for Sustainability, which is a morphing of the old Pollution Prevention (P2) Research Program. The PART review of the P2 Program found that the program was inadequate so EPA has reoriented the program to technology for sustainability. ORD would like the restructured program to be reviewed by the BOSC in December 2006-January 2007. The revised MYP on Technology for Sustainability was sent to the SAB for review. This review began on May 18, 2006, with a conference call and it will culminate in a face-to-face meeting in mid-June that will focus on the overall strategy for sustainability. The review will result in a consultation on the MYP. The Program Manager has been focused on the SAB review and would like some feedback on the MYP before drafting the charge for the BOSC program review. The retrospective aspect of the program review will focus on the P2 program and the prospective aspect will target the MYP for the next 5-8 years. The strategy for sustainability research and the MYP are available on the SAB Web Site. Dr. Farland will provide the Web address to the BOSC members so that they can review these two documents.

Dr. Giesy said that he is ready to move forward as soon as the charge is drafted. He asked if there was a new timeline for the review and how the SAB review impacted the BOSC's efforts. Dr. Farland responded that the timeline has not changed. The review will take place in the December 2006-January 2007 timeframe. He noted that the SAB review of the MYP is more narrowly focused than the program review. He agreed that it is important for the Subcommittee members to understand the goals of the review, and that should be possible by late June. Ms. Kowalski reminded the BOSC that there have been several instances where the SAB reviewed the MYP and the BOSC did a program review. She pointed out that the Land BOSC Program Review Subcommittee included an individual who was involved with the SAB review of the MYP. She asked if that approach was effective and Dr. Clark replied that it worked very well. He highly recommended using this approach in the future because that individual offered the Subcommittee some excellent insights.

#### Human Health Risk Assessment Subcommittee

Dr. Henderson asked if anyone had joined the meeting by telephone. Bruce Rodan (EPA/ORD/NCEA), Elaine Francis (EPA/ORD/NCER), and Bob Kavlock (EPA/ORD/NCCT) indicated that they were on the line.

Dr. Henderson reminded the BOSC members that Dr. Daston is the Chair of the Human Health Risk Assessment Subcommittee. She called for comments on the draft charge for this Subcommittee. She asked that the term "user-inspired" be deleted from the first page of the charge. Dr. Clark mentioned that he co-chaired the Human Health Subcommittee and the charge for that program review was similar to this one in length and complexity. The Subcommittee members for that review felt obliged to address all of the charge questions so the draft report was lengthy and the Executive Committee asked that it be shortened. He pointed out that this Human Health Risk Assessment Subcommittee charge will probably result in a lengthy report as well.

Dr. Lambert thought that the general public and state agencies should be included communications on page 5. He also thought the outcomes should be extended beyond the use of the assessments by EPA program and regional offices. Outcomes should include changes in laws and ultimately changes in risk.

#### Safe Pesticides/Safe Products Subcommittee

Dr. Harding pointed out that the term "user-inspired," to which Dr. Henderson objected, also appears in the draft charge for the Safe Pesticides/Safe Products Subcommittee. She asked if Elaine Francis was the National Program Director (NPD) for this program. Dr. Francis responded in the affirmative. Ms. Kowalski stated that Heather Drumm will serve as the DFO for the Subcommittee when she returns from maternity leave in July. Ms. Kowalski will serve as the DFO in the interim.

Dr. Harding asked Ms. Kowalski to review the process that is used for identifying candidates for the Subcommittee. Ms. Kowalski replied that the DFO develops a candidate list based on input from the Executive Committee, the Subcommittee Chair, ORD staff, program offices and regions, searches of editorial boards for journals, and Internet searches. The DFO casts a wide net to identify as many potential candidates as possible. The DFO then screens the list for potential conflicts of interest. The list is narrowed down to the top candidates, ensuring that it is balanced in terms of gender, culture, and geography. For example, there cannot be two members from the same institution. Each candidate must be approved by the Administrator's Office and invited to serve on the Subcommittee. Dr. Harding asked if Dr. Ryan could serve on the Safe Pesticides/Safe Products Subcommittee. Dr. Henderson asked Dr. Ryan if he would be willing to Co-Chair the Subcommittee and Dr. Ryan agreed. Ms. Kowalski asked Dr. Harding to notify her regarding the area(s) of expertise filled by Dr. Ryan so that she can focus on the other areas. Dr. Henderson thought that neurotoxicology should be added to the areas of expertise. Dr. Francis responded that it was not included because most of the neurotoxicology research is done by another program, specifically the Human Health Research Program. The emphasis of the Safe Pesticides/Safe Products Program is developmental neurotoxicology.

Dr. Harding asked if there were any comments on the charge questions. No comments were provided. Dr. Harding noted that the MYP had not been peer reviewed by an external panel. Is that still the case? Will the program review be conducted before the MYP is reviewed? Dr. Windom pointed out that this was the case with the Water Quality MYP. Dr. Henderson noted that the PM/Ozone MYP was not relevant for that program review because the program was changing. Dr. Francis said that ORD is in the process of updating the MYP but it has not been externally reviewed. Dr. Rodan added that the MYP for Human Health Risk Assessment has not been externally reviewed. That program is not in transition, however, so the MYP is relevant to the program. Dr. Lambert commented that outcomes should be addressed and they should go beyond regulations to improved health and environment. Dr. Henderson thought the required areas of expertise for this Subcommittee looked appropriate.

#### Homeland Security Subcommittee

Dr. Sayler reported that there is no draft charge for the Homeland Security Subcommittee and not much has happened since the last meeting. It has not been determined whether this should be a standing subcommittee or a subcommittee charged to conduct a program review.

Dr. Farland stated that the National Homeland Security Research Center (NHSRC) would like the BOSC to do a program review in August 2007. This gives the Board plenty of time to identify potential members and form the Subcommittee. It is not clear whether that Center needs a standing subcommittee. Dr. Farland pointed out that the standing subcommittee cannot be the subcommittee that performs the program review. Ms. Kowalski mentioned that additional time will be required to obtain security clearances for the Subcommittee members who will conduct the program review. She hopes to have the clearance process completed before summer 2007.

## Program Review Tool Workgroup

Dr. Henderson reminded the BOSC members that this workgroup was established to work with EPA and Office of Management and Budget (OMB) staff to develop a rating tool that would be useful and acceptable to the various parties. The workgroup members include Drs. Duke, Daston, and Weiss from the BOSC; Rob Strickland from OMB; and Jack Puzak, Jim Morant, John Johnson, Kevin Teichman, Lori Kowalski, Greg Sayles, and Hugh Tilson from ORD.

Ms. Kowalski noted that this is a workgroup and not a subcommittee. Therefore, the workgroup meetings are not subject to FACA requirements. The first meeting will be held June 15, 2006. The product developed by the workgroup will be submitted to the BOSC Executive Committee for review and comment. Dr. Lambert suggested including a member of the SAB on the workgroup. Ms. Kowalski pointed out that several members of the BOSC also are on the SAB. Dr. Clark suggested that the workgroup include the SAB DFO so that the DFO could inform the SAB about the progress of the workgroup and present the final product to the SAB members.

## **BOSC Issues**

Dr. Henderson asked if anyone had joined the meeting by telephone and George Alapas (EPA/ORD) and Greg Sayles (EPA/ORD) were on the line.

Dr. Farland noted that this is the 10th anniversary of the BOSC, stating that the Board was established in 1996. He then welcomed that new members to the Board and noted the new areas of expertise that they bring to the BOSC—Dr. Demerjian with air monitoring, Dr. Ryan with environmental health and biostatistics, Dr. Weiss with behavioral science, and Dr. Philbert with public health and toxicology expertise. He will be working with Ms. Kowalski this summer to fill the additional vacancies on the Board. Dr. Farland asked the members to identify any areas of expertise that they would like to add to the BOSC. He hopes to fill three positions this fall. The recruitment package will be developed in the next month or two.

Dr. Farland emphasized the importance and value of the program reviews conducted by the BOSC. The Administrator and Deputy Administrator have commented on these reviews a number of times. He reminded the Board that the Agency would like the reviews to be conducted on a 4-year cycle with a midterm check-in after 2 years. He pointed out that it has been about 2 years since the first program review was conducted, so it is time for the BOSC to start thinking about the 2-year check-ins for these programs. These mid-cycle check-ins could be scheduled the day before or after an Executive Committee meeting and one to three check-ins could be conducted concurrently. Dr. Farland asked the Board to provide input on the approach for these mid-cycle check-ins.

Referring to the MYPs, Dr. Farland indicated that these plans will be evergreen—continuing to evolve and change as the science and program goals change. ORD is seeking input from the BOSC on the MYP process. As mentioned earlier today, many of the MYPs are in transition. There will be a discussion later in the meeting on the standing laboratory/center subcommittees. The ORD Executive Council is very interested in pursuing the standing subcommittees to provide advice to the laboratories and centers. It is anticipated that these subcommittees would meet one to two times per year and participate in teleconferences as needed to address issues identified by the ORD Laboratory/Center Directors. Dr. Farland noted that one size does not have to fit all for these standing subcommittees because the needs of the laboratories/centers will vary.

With respect to filling the NPD positions, Dr. Farland reported that an offer has been made to fill the Human Health NPD, and the name should be announced shortly. The Agency expects to have the Ecosystems NPD identified by next week, and ORD is in negotiations with the potential Drinking Water NPD. He will keep the BOSC apprised of the Agency's progress on filling these NPD positions.

EPA has six Title 42 positions per year to fill for the next 5 years. The first five positions must be filled by September 2006 or the Agency may lose the capability to fill them. Three of the six positions (one bioinformatics and two systems biology) have closed. He hopes that these hires will move through the system quickly so ORD can focus on recruiting to fill the remaining three positions.

In January 2006, the Human Studies Review Board was established. Dr. Farland offered to invite the Chair of that Board, Dr. Celia Fisher from New York University, to brief the BOSC on the Review Board's responsibilities and activities. He noted that the human studies program is a large part of EPA's effort, and the Review Board covers epidemiological, observational, and intentional dosing studies. The Agency also has advertised for a Human Studies Review Official who will be responsible for signing off on these studies. An offer has been made to a physician who has a strong ethical background. This official will be part of the Office of the Science Advisor rather than ORD. Once that position is filled, Dr. Farland will inform the BOSC and provide the Board members an opportunity to interact with the Review Official.

Dr. Farland thanked everyone for coming to Las Vegas for the meeting to visit the NERL facility. Unfortunately, he will be unable to attend the site visit because he has to catch a flight to Vietnam for a meeting.

Dr. Henderson said that the BOSC would be interested in hearing from the Chair of the Human Studies Review Board. Dr. Sayler asked what input ORD is seeking with respect to the MYPs. Dr. Farland responded that ORD is hoping that the BOSC program reviews can help in the evolution of the MYPs. Because the program reviews are both retrospective and prospective, the subcommittees are evaluating the future direction of the programs, which is laid out in the MYPs. Dr. Sayler asked how to avoid the problem of a program review becoming just a review of the MYP. Ms. Kowalski replied that the Chair should make sure that the subcommittee stays on target and addresses the charge questions. The charge is important in guiding the review and end product.

Dr. Lambert asked about the status of the National Children's Study and the Vanguard Centers. Dr. Farland responded that the 2007 President's budget has no additional funding for the National Children's Study. There have been no changes since the last BOSC meeting. He does not know what Congress will do to change the budget, but it is possible that Congress could suggest that the funding be ramped up. It is more likely, however, that Congress will keep the funding consistent with the 2006 level, which will just be adequate to keep the Vanguard Centers in operation. Dr. Lambert asked if the Vanguard Centers will continue if EPA does not provide funding. Dr. Farland replied that EPA is willing to continue to provide the same level of funding, but that is only about \$2 million per year and that is not sufficient to keep the Vanguard Centers operational. Dr. Farland supports the work of the Centers and hopes they can continue until the full program is up and running. Unless there is some change in the 2007 President's budget, the Vanguard Centers will be phased out by the end of 2006 because of the lack of funding from

the National Institutes of Health (NIH). Dr. Ryan commented that EPA's contribution to the study is very small (only \$2 million), and \$69 million annually is needed to operate the Vanguard Centers.

Dr. Farland reported that the House Appropriations Committee has met on the EPA budget and added about \$22 million back into the 2007 President's budget; however, it is uncertain that this increase will hold up in the Senate. Dr. Lambert asked if there were any earmarks, and Dr. Farland replied that he was not certain. Dr. Lambert asked why EPA was placed under a different Appropriations Committee and Dr. Farland said that he did not know the reasoning behind the change, but it has been beneficial to EPA.

## **ORD Responses to Recent BOSC Reports**

Drinking Water Research Program (DWRP) Review Report

Dr. Greg Sayles, Acting NPD for Drinking Water, thanked the Drinking Water Subcommittee for their efforts in reviewing the program. He stated that in spring 2005, a binder of materials was provided to the Subcommittee and two conference calls (one administrative and one technical) were held. The face-to-face meeting of the Subcommittee was held in June 2005 in Cincinnati, Ohio. The meeting included 9 presentations and 55 posters, and ORD provided additional materials requested by the Subcommittee. The final report of the Subcommittee, dated October 2005, was transmitted to ORD on December 5, 2005. Dr. Sayles said that ORD welcomed the Subcommittee's compliments of the program and appreciated the findings and recommendations in the report. He highlighted one of the compliments contained in the report: "...the DWRP is relevant and critically important to EPA's mission in protecting human health and the environment. The program is focused on high quality research of national importance...". The charge topics included relevance, design, progress, quality, leadership, and communication. Dr. Sayles addressed comments on four of these charge topics—design, progress, leadership, and communication.

<u>BOSC Finding</u>: The rationale for partitioning of regulated and unregulated contaminants in the long-term goals (LTGs) is elusive. It does not facilitate multi-contaminant themes (source water protection, distribution systems, and water reuse).

<u>ORD Response</u>: The DWRP has drafted new LTGs. LTG 1 is to support mandated review and implementation of **existing** regulations. LTG 2 focuses on the source to tap continuum (source water  $\rightarrow$  treatment  $\rightarrow$  distribution). LTG 1 is focused on the short to medium range and LTG 2 is focused on the medium to long range and anticipatory issues. The Drinking Water MYP is being revised and these new LTGs will guide that revision.

**BOSC Recommendation**: The Subcommittee encouraged partnering with federal agencies and non-governmental organizations (NGOs) to leverage resources and skills.

<u>ORD Response</u>: The NPD will encourage partnering with federal agencies, NGOs, and other organizations. The NPD will develop a plan for partnering that ensures an equitable contribution by the partners.

BOSC Recommendation: The DWRP should support anticipatory research.

<u>ORD Response</u>: Anticipatory research is included in the new LTG structure and will be incorporated into the revised MYP. Also, the DWRP will continue to use the STAR Program (open-ended solicitations) to support anticipatory research.

<u>BOSC Recommendation</u>: "ORD's historical leadership role in drinking water research is eroding...ORD is strongly encouraged to develop a 'Science Leadership' mission statement."

<u>ORD Response</u>: The DWRP will develop a leadership mission statement and use it in resource and science planning.

BOSC Recommendation: The DWRP needs metrics to document the translation of products to impacts.

<u>ORD Response</u>: The DWRP helped lead the ORD effort to develop metrics. A pilot client survey was conducted in November 2005. The survey is being improved and expanded to cover use of products. The DWRP is continuing to explore different metrics and to improve the tools used to gather the data.

Dr. Sayles indicated that a draft of the revised MYP should be completed by October 1, 2006. The midterm check-in for the DWRP will be scheduled for late 2007-early 2008. The BOSC review has been crucial to the DWRP. It is being used to improve the program and it provided valuable input for the 2005 PART review. Specifically, the BOSC report was essential for addressing the R&D investment criteria and responding to Section 4 of the PART review.

Dr. Sayler, Chair of the Drinking Water Subcommittee, thanked Dr. Sayles and the DWRP for being so responsive to the Subcommittee's recommendations. He asked about the Subcommittee's recommendation concerning external review of cooperative agreements. Dr. Sayles replied that the DWRP follows the Agency's procedures for cooperative agreement competitions. Therefore, the program is constrained in responding to this recommendation; however, when the Agency procedures are reviewed, ORD will bring this recommendation to the table. Dr. Sayler noted that the report incorrectly reported the number of publications per person year after the Subcommittee had agreed to correct this at the face-to-face meeting. Dr. Sayler apologized for overlooking that error.

#### Management MYP Letter Report

Dr. George Alapas stated that the Management MYP was only 6 pages so he thought the BOSC's 1½ page letter report was an appropriate response. He agreed with all of the BOSC's comments, which focused on three major areas: (1) developing additional measures of success beyond ORD's ranking in the top 100 "Best Places to Work in the Federal Government"; (2) ensuring that all activities make a substantive contribution to more effective, efficient, and safe delivery of services in addition to improving ORD's reputation; and (3) providing more authority and resources to the ORD Management Council to make systemic changes that will result in ORD ranking in top 100 "Best Places to Work in the Federal Government." Dr. Alapas indicated that each of these themes will be reflected in the new version of the Management MYP. The BOSC's report was timely because ORD was in the process of revising the MYP. Although the revised MYP still includes ranking in the top 100 "Best Places to Work in the Federal Government" as a success measure, the plan also includes additional success measures linked to goals. ORD has developed a Web site on which the work plans are posted. Although Dr. Alapas concurred with the third item of providing more authority and resources to the Management Council, he did not think, given the budget constraints, that there would be any resources available. He stated that he thinks the BOSC will be pleased with the changes in the revised MYP.

Dr. Henderson asked if there were any questions or comments on the ORD response. There were none.

#### February 2005 Risk Assessment Workshop Letter Report

Dr. Farland stated that Bill Sette, a toxicologist in EPA's Office of the Science Advisor, prepared the ORD response to the letter report on the Risk Assessment Workshop. The workshop was held in February 2005 to solicit comments on Chapter 4 of EPA's staff paper on risk assessment principles and practices, "Use of Default and Extrapolation Assumptions." Dr. Farland said that EPA solicited input on the staff paper from various sources and the Agency is using this feedback to develop a strategy for the research program.

<u>BOSC Comment</u>: With the advent of the genomics era, it is becoming impossible to characterize in a quantitative way the relationships between effects at a molecular level and adverse outcomes on cell and organ function.

<u>ORD Response</u>: ORD agrees. The Agency has a Genomics Workgroup with several subgroups focused on quality assessment; data submission, management, and analysis; microbial source tracking; and training. The most recent effort for this workgroup has been to develop interim guidance for microarray-

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based assays for regulatory and risk assessment applications. A draft document is undergoing internal review by the Science Policy Council (SPC) and is expected to undergo external peer review this summer. The workgroup and the NCCT will work with the SPC to determine how the Agency is integrating genomics information into Agency decision-making. The new Title 42 positions will help lead these activities.

<u>BOSC Comment</u>: The BOSC recognizes that it is part of EPA's Computational Toxicology Program to participate in research and model development in systems biology. This activity needs to continue to be supported and its results incorporated into risk assessment practices when feasible.

<u>ORD Response</u>: ORD is continuing its work in this area. The next activity related to the staff paper will involve a consultation with the SAB this fall to discuss a number of ORD's key follow-up activities and plans in risk assessment practices. Current plans call for systems biology as one key area of focus for this meeting.

<u>BOSC Comment</u>: Many of the participants in the workshop provided examples of how advances in science can provide a foundation for risk assessment based on mode of action (MOA) and of the replacement of default uncertainty factors with empirical data.

<u>ORD Response</u>: ORD agrees. Recent efforts related to MOA analyses include internal communications to support implementation of mutagenic MOA analyses for carcinogenicity, and most recently, EPA has begun internal review of a paper from a Risk Assessment Forum technical panel intended to assist EPA risk assessors in determining whether data support a finding of mutagenic MOA for carcinogenicity. Efforts to use empirical data to replace uncertainty factors continue on a case by case basis, wherever possible.

**BOSC Comment**: Some of the presenters at the workshop suggested changes in toxicity test designs and quantitative risk assessment approaches need to be considered at this point.

<u>ORD Response</u>: With respect to toxicity test design, EPA, with ORD support, has a contract with the National Academies to review recent scientific advances and determine how they can be most effectively used to develop new testing strategies for conducting toxicity assessments. The committee will release a second report in fall 2006 that will provide a long-range vision and strategy for advancing the practices of toxicity testing and human health assessment of environmental contaminants. In its planned SAB consultation, ORD currently is planning to discuss probabilistic risk assessment for human health, expert elicitation, and possibly new initiatives to advance the practice of quantitative risk assessment.

**<u>BOSC Comment</u>**: We encourage EPA to continue its transparent communications about risk assessment practices.

<u>ORD Response</u>: EPA currently is planning a consultation with the SAB for this fall to review its follow-up activities to the entire staff paper, with a focus on a number of key issues, including, as now planned, systems biology, and a number of approaches to elements of quantitative risk assessment. ORD will keep the BOSC informed as plans for the meeting evolve.

Dr. Farland noted that Dr. Gray is interested in how to characterize and communicate uncertainty in risk assessments and he wants ORD to develop a roadmap for the activities that will be undertaken to address this issue. He thanked the BOSC for convening the workshop and for publishing the summary paper and proceedings of the workshop.

Dr. Henderson commented that this was not a consensus workshop; rather it was a free exchange of ideas. She stressed the importance of defining uncertainty. She found a good definition in a paper by Chiu, which states that "uncertainty is the lack of knowledge that can be reduced by additional data." She added that variability cannot be reduced, it only can be described.

Dr. Sayler asked if the ORD responses to the reports could be sent to the members of the Subcommittees. Ms. Kowalski stated yes, the responses are posted on the BOSC Web Site and are available to the public. She added that an e-mail could be sent to the Subcommittee members to notify them that the ORD

response has been posted on the Web site and provide them with the URL for the site. When no additional comments were offered, Dr. Henderson thanked ORD for these responses to recent BOSC reports.

## **Subcommittee Chair Handbook**

Ms. Kowalski explained that the BOSC Handbook for Subcommittee Chairs was prepared to provide guidance to the BOSC Subcommittee Chairs and DFOs. This version of the handbook includes the changes that were suggested at the February 2006 meeting. Some additional revisions have been made that were not discussed at that meeting; for example, Web links have been added. The handbook highlights the role of the Subcommittee Chair and summarizes the relationship between the Subcommittee and the Executive Committee. It is written as a guide to the Subcommittee Chair but it also applies to the Executive Committee. The handbook addresses why subcommittees are formed, the roles and responsibilities of the key parties, guidelines for report summaries, an overview of FACA, common charge questions for BOSC reviews, lessons learned in conducting program reviews, and an introduction to ORD.

Dr. Henderson asked for comments on Chapter 1 of the handbook. No comments were received. She then asked for comments on Chapter 2, and no one had any comments. Dr. Henderson asked for comments on Chapter 3. Referring to Section 3.3, Ms. Kowalski pointed out that the program review reports, once they have been approved by the Executive Committee, are considered BOSC reports. She noted that the Subcommittee cannot transmit the report to ORD; it must be transmitted by the Executive Committee.

Dr. Windom suggested adding a reference to Appendix C in Section 3.2 Key Decisions To Be Made. He thought this should be in boldface type because Appendix C contains some important information.

Referring to Section 3.1, Dr. Demerjian asked if there is a process for identifying new areas of interest. How does the Board identify important areas that are not being addressed by ORD? Dr. Henderson responded that ideas often are brought up in discussions during Executive Committee meetings. If the Board has an interest in pursuing the idea further, the Chair requests a presentation on the topic and the BOSC discusses the issue in an effort to determine how the Board could provide advice to ORD. Dr. Farland mentioned that communications had been a recurring theme at BOSC meetings, so after a presentation, the Board established the Communications Subcommittee that organized a workshop on best practices and prepared a report.

Dr. Henderson asked if there were additional comments on Chapter 3, and there were none. There also were no comments on Chapter 4. With regard to Chapter 5, Dr. Henderson stated that its purpose is to ensure some consistency in the summary sections of the BOSC reports. Referring to Section 5.2, Dr. Clark commented that it may be very difficult to summarize a lengthy, complex charge in two paragraphs. That was a challenge for the Human Health Subcommittee. Dr. Henderson agreed, stating that there has to be some flexibility. Dr. Duke asked if the summary is intended to stand alone or is it intended to capture highlights of the report. Dr. Henderson responded that she preferred the summary to stand alone. Dr. Harding asked if all of the recommendations should be included in the summary, and Dr. Henderson replied in the affirmative. Dr. Giesy noted that the summary section is 20 percent of the STAR/GRO Fellowship Subcommittee Report. If a document is 30 pages long, the summary should not be 10 pages. He pointed out that most individuals would read a 25 page report as long as it is concise and not redundant. The summary should be short, about 1-2 pages and it should capture the highlights of the report.

Dr. Windom said that the Water Quality Subcommittee had a difficult time following the guide for the summary. Therefore, the Subcommittee developed a table to summarize the findings and recommendations. For the section on the charge, the summary should only include the major themes and

it should not include the detailed questions. Dr. Windom suggested adding a statement in Chapter 5 that instructs the Subcommittees to avoid redundancy in the reports. Dr. Giesy said that he views the handbook as a living document and it should be updated periodically as the BOSC completes more reviews, perhaps once a year. He recommended that the handbook include a simplified diagram that illustrates the process for a program review and another diagram for a letter review. Dr. Windom proposed the use of a text box in the reports to list the goals of the program. This requirement should be included in Chapter 5 of the handbook. Dr. Duke thought it might be helpful to include a draft timeline to give the new Chairs an idea of how long the process takes, particularly the time required to form a subcommittee. Ms. Kowalski responded that she works with the DFOs to help them through the process of establishing a new subcommittee but there are many steps and approvals in the process. She agreed to include some information on timing in the handbook. Dr. Clark indicated that he had some editorial comments on the handbook and he will provide them to Ms. Kowalski.

Dr. Henderson called for a motion to approve the handbook with the suggested changes. Dr. Windom moved to approve the handbook and Dr. Duke seconded the motion. The handbook was approved unanimously by the BOSC.

#### **Standing BOSC Laboratory/Center Subcommittees**

Dr. Henderson asked for comments on the draft generic charge for the standing Laboratory/Center Subcommittees. This draft charge was prepared by Dr. Daston with input by Dr. Kavlock. Dr. Henderson noted that there currently is only one standing subcommittee, the Computational Toxicology Subcommittee. All of the program and other BOSC reviews have been conducted by non-standing subcommittees. She asked Dr. Farland to elaborate on the purpose of these subcommittees and the frequency with which they will meet.

Dr. Farland stated that there are seven ORD laboratories and centers (three laboratories and four centers), including the NCCT, for which a standing subcommittee already exists. ORD currently has the resources to form four new standing subcommittees. Susan Peterson will serve as the DFO for three of the standing subcommittees, and Heather Drumm will be the DFO for the fourth standing subcommittee. Dr. Giesy asked if the standing subcommittees would include individuals who are not serving on the Executive Committee, and Dr. Henderson replied that both Executive Committee members and others would serve on the subcommittees. Dr. Clark confirmed that the Computational Toxicology Subcommittee included both.

Dr. Farland proposed that the standing subcommittees meet on a periodic basis to provide advice and counsel to the laboratories/centers. Since its inception, the BOSC has conducted two reviews of the ORD laboratories/centers. For these reviews, the BOSC developed a list of self-study questions and the laboratory/center prepared a response to the questions and the subcommittee conducted a site visit to the laboratory/center. Although these reviews were helpful, the Executive Council sees the standing subcommittees as playing a different role. These new subcommittees will provide ongoing advice about various issues and concerns of the laboratories/centers. These subcommittees will meet possibly two to three times a year, depending on the needs of the specific laboratory/center. He suggested that the first meeting be 2 to 3 days to allow time for the subcommittee members to get acquainted with laboratory/center staff and familiar with the activities being conducted. He explained that each laboratory/center conducts research that supports a number of MYPs and programs so this will not overlap with the program reviews. The efforts of these new subcommittees will focus on how the laboratories/centers are managing their multidisciplinary programs.

Dr. Farland envisions these subcommittees as having five to seven members, including one or two Executive Committee members. He proposed that, after the initial meeting, the meetings be 1 to 1 ½ days with agendas that focus on a specific set of issues and questions for discussion.

Dr. Henderson proposed that the new standing subcommittees meet once each year and address issues and questions as they arise by teleconferences. This would allow the subcommittees to provide timely, crucial advice without the demand of traveling several times a year to meetings. Dr. Windom agreed that the new subcommittees should meet once a year and there should not be a complicated list of charge questions to be addressed at each meeting. He thought that the level of commitment for meeting two to three times a year would be too difficult for the Executive Committee members.

Dr. Clark proposed that these subcommittee meetings be considered more like consultations than program reviews. Dr. Giesy suggested eliminating the requirement of a report for these subcommittee meetings. Ms. Kowalski responded that the standing subcommittees will be subject to FACA requirements but the Agency envisions keeping these meetings informal and the resulting report should be something that is useful to the BOSC and EPA. She reiterated that a subcommittee cannot transmit anything directly to ORD, so the Executive Committee needs to discuss how the subcommittee can provide advice that needs to go through the Executive Committee. Ms. Kowalski must report the number of Executive Committee and subcommittee meetings and the products generated. There has to be some type of documentation for the meetings.

Dr. Giesy asked if the Executive Committee could be expanded. Ms. Kowalski replied that it could include only 15 members and EPA is working to fill the vacant positions. Dr. Demerjian asked if the product could be a letter report and Ms. Kowalski responded that a letter report would be sufficient. Dr. Farland agreed that these meetings will be more like consultations than site visits. The subcommittee members will engage in a dialog on one or two topics and EPA staff will glean what it can from that dialog. The subcommittee would report to the Executive Committee what was discussed at the meeting. Dr. Henderson mentioned that the Clean Air Scientific Advisory Committee (CASAC) does consultations for which it provides no letter report. The CASAC does prepare a letter, however, stating that a consultation was held. Dr. Windom commented that the major goal of these standing subcommittees appears to be timely communication.

#### **Public Comment**

Dr. Henderson paused the discussion at 4:00 p.m. to ask if there were any comments from the public. No comments were presented so Dr. Henderson resumed the discussion of the standing subcommittees.

## **Standing BOSC Laboratory/Center Subcommittees (Continued)**

Following up on Dr. Windom's comment, Dr. Giesy stated that the members of the standing subcommittees will have the opportunity to review the efforts of the laboratories/centers over time, which will make them more knowledgeable and able to provide better advice. Speaking from his experiences on the Human Health Subcommittee and the Computational Toxicology Subcommittee, Dr. Clark noted that some knowledge of the research programs will be helpful to the members serving on the laboratory/center subcommittees.

Dr. Lambert pointed out that, at the February meeting, Dr. Peter Preuss indicated that the National Center for Environmental Assessment (NCEA) needs advice that will improve the science. He wants scientific input rather than management input. Dr. Henderson replied that the subcommittee could provide both and it will be up to the Laboratory/Center Director to inform the subcommittee what is needed. Dr. Windom did not think the standing subcommittees would have the expertise needed to address all science issues.

Dr. Demerjian stated that the subcommittee could help with strategic thinking. Is the laboratory/center going in the right direction? Is it conducting its research in the most effective way? The subcommittee also could provide advice on priorities such as what efforts to cut when there are budget reductions.

Dr. Giesy asked for some history on the Computational Toxicology Subcommittee. Dr. Clark reported that the Subcommittee was established as the Center was getting started. It has provided the Center Director access to an advisory group off of which he could bounce ideas. The issues to be addressed by the Center kept expanding, so the Subcommittee provided advice on how to grow the program. The Subcommittee has had one face-to-face meeting and one conference call. The second meeting is scheduled for later this month. There now are six members on the Subcommittee. Following the first meeting, the Subcommittee prepared a letter report to which ORD submitted a response. The purpose of the conference call was to finalize that report. Ms. Kowalski mentioned that the letter report and ORD's response are posted on the BOSC Web Site.

Dr. Giesy asked if there were any other external advisory groups accessed by the NCCT. Dr. Farland responded that there are other sources of advice available to the Center and the other laboratories and centers. For example, the laboratories/centers have divisional reviews by a committee of external experts every 2-3 years. They also hold national/international workshops to get advice on scientific issues. The standing subcommittee may advise the laboratory/center when it is appropriate to hold such a workshop. There are numerous sources of external advice; the standing subcommittees are meant to be an informal means of obtaining that advice and allowing opportunities for timely discussion of various issues and topics.

Dr. Harding mentioned that a number of the ORD laboratories/centers have staff in several locations. Will the subcommittees meet at the different locations? Dr. Farland replied that the Directors probably will bring the managers from the other locations to the meeting, but that would be up to the Director.

Dr. Henderson stated that the draft charge for the standing subcommittees is an attempt to define the activities of the subcommittees. She asked for comments on the draft charge. Dr. Clark suggested that the charge refer to areas rather than questions; for example, change the head Charge Questions to Areas of Consultative Responsibility. Dr. Giesy thought consultation rather than evaluation should be the focus of the charge. He proposed replacing the word "evaluation" with "consultation" throughout the charge. Dr. Windom asked if the Laboratory/Center Directors had seen the draft charge. Ms. Kowalski replied that only Dr. Kavlock had seen it and provided input. Dr. Windom thought the other Directors should have an opportunity to comment on the draft. Dr. Henderson suggested inserting "and scientific programs" after "Multi-Year Plans" in the last sentence under the Background section. Dr. Giesy asked that the word "oversight" be removed from the charge title and replaced with "consultative." The subcommittees will not be overseeing the laboratories/centers so that wording is inappropriate. He had some additional editorial changes that he will provide to Dr. Henderson. Dr. Giesy did not want to vote on the draft charge until it had been revised. Dr. Henderson agreed to incorporate the suggestions into the draft and distribute it for review tomorrow morning. Dr. Windom asked that the draft be sent to the Laboratory/Center Directors. Ms. Kowalski stated that as soon as the draft is approved by the BOSC it will be sent to the ORD Directors for comment. She did not know whether Dr. Johnson had an opportunity to review the draft charge before he left for Botswana so he may have some comments.

Dr. Henderson asked for volunteers to serve on the standing subcommittees. Dr. Demerjian said that he is familiar with NERL and would be willing to serve on that subcommittee. He wanted to make sure this would not be a conflict of interest. Ms. Kowalski said that she would look into it and get back to the Board. Dr. Demerjian asked if additional experts could be added to the standing subcommittee should the need arise. Ms. Kowalski responded that the members of the subcommittee can be changed with time. Each member's appointment is for 1 year; at that point they can be invited to serve for another year or replaced with someone else. She noted that it does take some time to get new members invited to serve. Dr. Ryan said that he would be willing to serve on the National Health and Environmental Effects Research Laboratory (NHEERL) Subcommittee. Dr. Giesy volunteered to serve on the NCEA Subcommittee. Dr. Sayler would like to serve on the NHSRC Subcommittee. Dr. Farland reminded him that he cannot serve on the subcommittee that reviews the program and the standing subcommittee. Dr. Sayler said that he would prefer to chair the subcommittee that conducts the program review. Dr. Giesy stated that he has a security clearance that could be activated. If it would be helpful, he could switch to

the NHSRC Subcommittee. Dr. Henderson suggested that Dr. Philbert might be able to chair the NCEA Subcommittee. She agreed to present that possibility to him.

Ms. Kowalski indicated that the areas of expertise for these subcommittees must be identified. She suggested a conference call with the DFO, Subcommittee Chair, and the Laboratory/Center Director to discuss the needed expertise, the size of the Subcommittee, the frequency of meetings, and what issues will be addressed initially by the subcommittee.

## **Futures: Project Horizon**

Ms. Anita Street, who participated by telephone, provided an overview of Project Horizon, described the current status of the program, and identified some next steps.

Project Horizon brings together U.S. Government global affairs agencies for joint, scenario-based strategic planning. The strategic intent of the project is to develop realistic interagency strategies and identify capabilities in which the U.S. Government should invest to prepare for the unforeseen threats and opportunities that will face the nation over the next 20 years. The intended results are: (1) structured interagency strategies and solutions stress-tested for robustness, (2) knowledge transfer to enable individual agencies to customize the scenarios to conduct internal planning, and (3) a foundation for an ongoing interagency planning process. The project participants include U.S. Government senior executives, strategic planners, and subject matter experts together with select academics and private sector participants. The Core Team members include: State (lead), Agriculture, Defense, Energy, Homeland Security, Agency for International Development, Health and Human Services, Office of the Director of National Intelligence, Treasury, EPA, Commerce, Labor, Millennium Challenge Corporation, and National Defense University.

The Core Team conducted research and expert interviews across targeted thematic and regional categories and identified an initial list of "Drivers" to be explored in the planning effort. The Team distilled the initial Driver set into four "Dimensions" that define the boundaries of the "Planning Space." The Team then created a "Planning Space" of 16 possible scenarios based on all permutations of these Dimensions. A set of five proposed scenarios to be detailed extensively for use in the planning workshops were identified.

Research and interviews provided insight into the Drivers of the U.S. Government global affairs operating environment over the next 20 years. Input from these activities yielded a rich list of issues to be examined in the scenarios and Drivers from which Dimensions were derived. Team members conducted research on key topics and geographical areas and the results were presented during the interview and research synthesis workshop held October 18-21, 2005. Approximately 110 internal interviews were conducted across all participating agencies. Additionally, approximately 90 external interviews were conducted across academia, NGOs, media, think-tanks, and the private sector.

The key topics and geographic areas included:

- ♦ Nuclear/weapons of mass destruction (WMD) proliferation and arms trade
- ♦ Energy, supply/demand, hydrocarbon alternatives, etc.
- ♦ Global trade and investment
- ♦ Critical global business trends
- ♦ Climate change/global warming/environment/geological issues
- ♦ Global disease/plagues
- ♦ Demographic/migration
- ♦ Food/water/natural resources
- ♦ Terrorism/regional instability
- ♦ Poverty and economic development

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- ♦ U.S. and global economy
- ♦ Space/Antarctica/ocean resources
- ♦ Scientific and technology breakthroughs
- ♦ Ideology/beliefs/religion
- ♦ Political structures
- ♦ Social structures
- ♦ Media/communications/information flows
- ♦ Cyber security
- ♦ Rising powers
- ♦ Critical countries (e.g., China, India, Russia) and regions.

The Drivers were merged and collapsed into Dimensions. Some of the Drivers identified were economics and finance, geopolitics, natural resources, population and demographics, society and culture, and science and technology. Some of the resulting Dimensions were challenge to nation state power and influence, gap in the global standard of living, U.S. economic competitiveness, and perception of serious threat to U.S. security and/or quality of life.

Ms. Street explained that Drivers are forces (often interdependent) that literally drive change, such as technology, economics, population, culture, and globalization. For an automobile manufacturer, Drivers may be the cost of energy, state of the transportation infrastructure, or tariff and non-tariff barriers. The Project Horizon Team identified more than 350 potential Drivers. The Drivers helped to identify the planning space Dimensions. A subset of important Drivers formed the backbone of the scenario development. More than 75 Drivers were selected for scenario development, which meant that the "state" of those Drivers had to be included in all the scenarios to be used. For example, the cost of energy and the availability of alternatives was a required Driver that must be discussed in each scenario.

Dimensions define the boundaries of the "Planning Space." The scenarios will be found within those boundaries. Although the initial list of Drivers could be anything the planning organization thinks is important, Dimensions have specific rules and bring rigor to the 20-year planning "space." Dimensions must: (1) be at a very macro-level, (2) be relevant to the organization and its operating environment, (3) be beyond the organization's immediate control, (4) be something the organization is willing to use as an independent variable (willing to "freeze" it as an axiomatic assumption), and (5) have a "future state" that is not predictable, but can vary widely.

Ms. Street defined a number of the Dimensions identified by the Team. *Challenge to Nation State Power and Influence* is the relative power, globally, of nation-states in the international arena, as compared to both other governmental entities (e.g., European Union, World Trade Organization [WTO], North Atlantic Treaty Organization [NATO], United Nations) and nongovernmental entities (e.g., business organizations, NGOs, criminal enterprises, tribes, other affiliation groups, and individuals). This Dimension is said to be '*High*' when the dominance of the nation-state in the international arena is seriously challenged by other governmental and nongovernmental entities. This Dimension is said to be '*Low*' when the dominance of the nation-state in the international arena is not seriously challenged by other governmental and nongovernmental entities.

*U.S. Economic Competitiveness* refers to the productivity of the U.S. economy as a whole relative to the rest of the world. The components of competitiveness may include: innovation, infrastructure, research and development, education, access to energy and natural resources, availability of capital, and fiscal health. This Dimension is said to be '*Strong*' when the U.S. economy is doing well in the global marketplace. This Dimension is said to be '*Weak*' when the U.S. economy is struggling in the global marketplace.

The Global Standard of Living Gap is the relative difference between the consuming power of the "haves" and "have-nots." Consuming power includes consumption of all types of goods and services (including education and cultural goods), whether purchased or provided by a third party (such as

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government or employer). These differences may be within or between countries, or as a global phenomenon. This Dimension is said to be '*Increasing*' when the gap between the consuming power of the "haves" and that of the "have-nots" is widening. This Dimension is said to be '*Decreasing*' when the gap between the consuming power of the "haves" and that of the "have-nots" is narrowing.

The threats considered in the *Perception of Serious Threat to U.S. Security and/or Quality of Life* Dimension are those that rise above the background noise of everyday life and command the attention of the population for an extended period of time. This Dimension is said to be '*High*' when there is significant and long-term public concern regarding perceived threat(s) to U.S. well-being. Actual threat(s) may vary greatly from this perception. This Dimension is said to be '*Low*' when public concern over potential threat(s) to U.S. well-being is not significant beyond those considered normal to everyday existence. Actual threat(s) may vary greatly from this perception. This Dimension describes the U.S. general population's level of anxiety regarding perceived threats to the national security, health, safety, stability, and viability of the U.S. socio-economic and political system. This can include diverse threats such as military, economic, terrorist, environmental, or disease.

The four dimensions yielded 16 possible scenarios. Of the 16 scenarios, five were selected based on the following criteria: (1) they provide interesting, unexpected and challenging operating environments; (2) as a set, they capture the range of important opportunities and challenges; and (3) they illuminate the key themes and ideas from the research and interviews. The five scenarios selected were: *Asian Way*, *Congagement, Lockdown, Be Careful What You Wish For*, and *Profits and Principles*. Descriptions of each of the five scenarios follow.

#### **Asian Way**

Challenge to Nation State Power and Influence	Gap in Global Standard of Living	U.S. Economic Competitiveness	Perception of Serious Threats to U.S. Security and Quality of Life
High	Decreasing	Weak	Low

In 2025, the world economy is increasingly dominated by Asian mega-corporations that are expanding at the expense of the formerly dominant American and European military/economic powers. The "Asian Way" of conducting business and national affairs in more discreet, shielded ways, through subtle personal networks, rather than in the Western mode of at least apparent insistence on transparency, disclosure, democratization (in politics), has yielded clear advantages both in the marketplace and in national affairs over the Western-style capitalism of the post-World War II era. America is trying to dig itself out of the fiscal and economic hole caused by its simultaneous attempts to insulate itself from terrorism (mainly successfully), fund the retirement of its elderly, maintain military supremacy, and keep its tax rates low. The U.S. public feels secure from any imminent threat, but feels uneasy about what appears to be the end of the era of American dominance. While Asian governments are increasingly transferring power to influential, opaque corporate interests, in the United States, the federal government has found itself increasingly politically paralyzed and losing influence to state and local governments and corporations, all of which are cutting deals with the new Asian mega-corporations. Asia is increasingly where the action is—in terms of business, culture, and even political power.

## Congagement

Challenge to Nation State Power and Influence	Gap in Global Standard of Living	U.S. Economic Competitiveness	Perception of Serious Threats to U.S. Security and Quality of Life
High	Decreasing	Strong	High

This is a world in which political and economic power increasingly are organized regionally, rather than globally. It is a vibrant, dynamic, tense, and highly competitive world with multiple points of friction. These dynamics create a continually shifting mixture of both tension and trade, both confrontation and engagement, or "congagement" for short. The emerging regional blocs revolve around three major power centers—the United States, the European Union, and China. Each of these is increasingly sharing power with regional authorities. The power blocs are not monolithic, however. The other major players—Brazil, Russia, and India—shift among them opportunistically to varying extents. The remaining nations in Africa, the Middle East, and Central Asia with resources and/or major markets are the objects of energetic competition; while those nations with few resources or markets are neglected. Within the United States, there is a new focus on the Americas. The global commons are in jeopardy as there are few effective mechanisms for managing global issues. Trade, commerce, and capital flows still benefit from a legacy global architecture, but new investments follow the strong new intra-regional economic and political relationships.

#### **Lock Down**

Challenge to Nation State Power and Influence	Gap in Global Standard of Living	U.S. Economic Competitiveness	Perception of Serious Threats to U.S. Security and Quality of Life
Low	Increasing	Weak	High

This is a multi-threat world marked by persistent terrorism, nuclear proliferation, and the most challenging economics the United States—and the world—have faced in more than 50 years. The United States turned heavily defense, protectionist, and isolationist following WMD attacks launched by a new, virtual radical Islamic terror network. This new posture has had a profoundly negative impact on economic and social life in the United States, with harsh effects across the global economy. Europe also is a target of terrorist violence although the frequency and human cost have been considerably less. Globally, nuclear proliferation continues unabated and an uneasy balance of terror hangs over the Middle East. Many developing countries are collapsing, without export markets and foreign aid. China is the principal victim of the United States lock down and its economic and political desperation is now taking an ominous turn—toward Taiwan.

#### Be Careful What You Wish For

Challenge to Nation State Power and Influence	Gap in Global Standard of Living	U.S. Economic Competitiveness	Perception of Serious Threats to U.S. Security and Quality of Life
Low	Decreasing	Strong	Low

Not without its problems to manage, 2025 is a world of excitement, opportunity, freedom, and technological wonders. Democratic governments with some level of engaged and informed citizenry have emerged and prospered in all regions of the globe. Nation-states still command the global political landscape, but conflicts are low level and usually resolved through peaceful means. The global economy is growing and wealth is being distributed more evenly than ever before, although significant areas of poverty remain. The world faces a globally acknowledged environmental crisis, especially in the Pacific Ring of Fire, created by human and natural causes. Due to environmental stability concerns, manufacturing sites and transportation systems are now spread across the globe. A U.S.-initiated worldwide movement exerts a strong influence on government, social, and technological agendas. The United States is finding that participating and leading in a world made up of activist Fellow democracies is chaotic and challenging in unexpected ways.

**Profits and Principles** 

Challenge to Nation State Power and Influence	Gap in Global	U.S. Economic	Perception of Serious Threats to U.S.
	Standard of Living	Competitiveness	Security and Quality of Life
High	Increasing	Strong	High

Across much of the world, a new culture of global capitalism is fueling rapid economic growth, increasingly integrated markets, and dynamic technological innovation. Foreign policy is strongly influenced by business leaders who are pulling the strings of increasingly powerful international bodies. The U.S. economy is thriving, but social safety nets have disappeared as the global business drive for profits ruthlessly discards those who cannot (or do not) contribute. An emerging moderate Pan-Islamic movement with a message that Islam cares (while global capitalism does not) is attempting to fill the void, and has gathered partners among other religious and social movements. Leaders of the new movement are benefiting from high income from hydrocarbon energy resources and are using some of this wealth to provide for those left behind. Although the top tier of Americans have benefited tremendously from hyper-capitalism, many others have not and the global clash between profits and principles is causing the business leaders high anxiety. Optimists see these diverging paths as complimentary and useful. Pessimists worry that these divergent paths could end up on a collision course, with profound consequences for the United States and the world.

Ms. Street stated that testing the scenarios against the key Core Team Drivers (energy, U.S. Government fiscal condition, health/disease, conflict/terror, global perception of the United States, trade/protectionism, U.S. sense of trust in Government, education/science/technology, and mobility/migration) revealed that all of the Drivers were relevant in all of the scenarios. In addition, all of the Drivers varied significantly in the five scenarios.

The major outputs of the project include: (1) interagency platform scenario set, (2) workshops, (3) interagency studies overview report, (4) proposed strategic interagency capabilities, (5) knowledge transfer toolkit and workshops, (6) final deliverable package (all final materials and report), and (7) agency-specific findings (optional plans for each participating agency).

For the interagency synthesis review, the approximately 150 capabilities identified in the workshops were grouped into "like" capabilities. The robust, self-standing capability clusters were identified and their core elements were defined. Draft capability descriptions were developed, including implementation considerations, and these were stress-tested in the five scenarios. Ms. Street identified what remains to be done—the capability set must be confirmed by the Senior Principals Board, the final report drafted, and the communication and implementation approaches determined.

Ms. Street reported that Phase I: Scenario Development—which included research, interviews, and scenario development—was completed in March 2006. The workshops component of Phase II: Interagency Planning was completed in April 2006, but the interagency synthesis efforts are expected to continue until July 2006. Phase III: Knowledge Transfer is just beginning. This phase includes the development of a toolkit, knowledge transfer via workshops, and optional agency-specific customization and planning.

The next steps are to: (1) prepare the final report, (2) approve and communicate the final report, (3) complete knowledge transfer (finalize the Project Horizon Planning Toolkit and conduct knowledge transfer workshops, (4) develop capability implementation plans, (5) conduct agency-specific analysis, and (6) determine the approach to institutionalizing the process. The next step for ORD is to integrate the results into futures efforts by scanning for issues that emerge from the scenarios, prepare science updates for the Administrator related to Project Horizon emerging issues, and participate in post-Project Horizon network activities as they continue to develop.

Dr. Henderson asked about the goal of Project Horizon and Ms. Street responded that the project is intended to improve strategic planning. It should identify some actions that can be taken today to prevent future problems. Dr. Sayler commented that the project is similar to the exercises used by global industry. Ms. Street replied that Shell and other companies have used scenario planning for decades. The Government has struggled with using it because agencies are constrained by regulations and authorities.

Dr. Harding noted that many aspects of the scenarios already exist. How can EPA make a difference and bring about change? Ms. Street responded that the Administrator has shown some interest in this project. Dr. Henderson asked about the budget for Project Horizon and Ms. Street stated that the EPA funding for the project was \$30K plus 30-50 percent of her time. Dr. Duke asked if the project has used the Millennium Ecosystem Assessment. Ms. Street said that she is aware of it but has not explored the possibilities yet. Dr. Windom asked if there was political support for this effort. Ms. Street responded that the support is still unknown. She hopes to find out more at the June 5 meeting.

Dr. Clark asked if global climate change was the only ecological scenario in the project and Ms. Street replied that it was the only one, stating that it was difficult to include more because only catastrophic events were considered. There was discussion of farming and the effects of distributed manufacturing, but these did not enter into the scenarios. Dr. Farland said that he participated in the interviews and many of the environmental scenarios had to do with the environmental impacts of energy development and water issues. These did not play that well, however, in the overall scenario exercise. Ms. Street commented that there was a lack of attention to both the positive and negative consequences of technology in the five scenarios. Dr. Windom mentioned the shift from fossil fuel to nuclear energy, stating that this is one area that should be addressed.

#### **SAB Activities**

Dr. Lambert distributed the Fiscal Year 2006 list of SAB Staff Office Advisory Projects to the BOSC members. He attended the SAB budget meeting this year, noting that the discussion was at a much higher level than in past years. The next SAB meeting will be held June 22-23, 2006 in New York City in conjunction with Region 2. The SAB already has held meetings in Regions 9, 6, and 5. Dr. Lambert said that there have been some very interesting presentations by the regional offices at these meetings.

Referring to the activities requested by the Office of Air and Radiation (OAR), Dr. Lambert noted that CASAC is well represented. He mentioned that lead and radiation appear to be the dominant themes. Dr. Henderson noted that CASAC will be reviewing the Lead National Ambient Air Quality Standards (NAAQS) Environmental Assessment and the ORD criteria document. CASAC also is reviewing the Lead NAAQS Exposure and Risk Scoping Plan. She was not certain if there were any combined SAB-BOSC activities.

Dr. Clark asked about the Ecological Risk Assessment Approach activity and Dr. Farland responded that this is an SAB-initiated study. The SAB held a workshop on approaches to risk assessment in February 2006, and this is a follow-on to that effort. Dr. Farland mentioned that the SAB will undergo a PART review in 2006.

When there were no more comments or questions, Dr. Henderson thanked everyone for their participation. She reminded the Board members that tomorrow's meeting would be held at the NERL facility. The meeting was recessed at 5:30 p.m.

## **Friday, June 2, 2006**

The meeting was reconvened at 8:45 a.m. at the NERL facility on the campus of the University of Nevada–Las Vegas (UNLV). Dr. Henderson expressed her appreciation to the laboratory staff for inviting the BOSC for a site visit.

#### Overview of NERL-Las Vegas

Ms. Jane Denne, Deputy Director of the Environmental Sciences Division (ESD) of NERL, welcomed the BOSC members. She provided an overview of the Division followed by two presentations: Landscape Ecology Studies in the Western United States by Daniel Heggem, Acting Chief of the ESD Landscape Ecology Branch, and Modeling Human Exposures by Dr. Curt Dary, Chief of the NERL-Las Vegas Exposure and Dose Research Branch of the Human Exposure and Atmospheric Sciences Division.

NERL provides information to increase the accuracy of EPA's exposure and risk assessments for factors that stress the environment such as chemicals and changes in land and water use. NERL also evaluates innovative technologies to improve exposure assessment and provides information on stressor sources, pollution transport and fate, and human exposure to pollutants. NERL's ESD conducts research, development, and technology transfer programs on environmental exposures to ecological and human receptors. The Division develops and evaluates methods to characterize chemical and physical stressors, with emphasis on ecological exposure. ESD develops landscape and regional assessment capabilities through the use of remote sensing and advanced spatial analysis techniques. ESD also conducts research on analytical chemistry methods for Superfund and water programs and applies advanced monitoring/characterization technology to issues involving surface and subsurface contamination.

Dr. Lambert asked about the number of employees at the laboratory. Ms. Denne replied that there are about 80 employees in the ESD, some of whom are located at the Research Triangle Park facility in North Carolina and others in Reston, Virginia. About 60 of the 80 employees are scientists. Dr. Henderson asked how many of the scientists are lead investigators. Ms. Denne responded that approximately 35 of the 60 scientists are lead investigators. Dr. Lambert asked if there is much interaction with the University of Nevada-Las Vegas. Ms. Denne replied that there is a good level of interaction and that there are a number of formal and informal collaborations with the university and laboratory. She mentioned that there are other components of EPA located at the Las Vegas facility, including a finance office, human resources, and members of the Environmental Response Team-West, the OAR Radiation and Indoor Environment National Laboratory, and ORD's NHSRC. Dr. Harding asked if any of the scientists have faculty appointments at the university. Ms. Denne replied that several staff members have or have had an adjunct appointment and that there are a number of staff members who have made presentations or taught classes at the university. Dr. Henderson asked if any of the graduate students work at the facility. Ms. Denne responded that there are a few post-docs at the laboratory and that a number of EPA employees have employed graduate students. Dr. Giesy asked about collaboration with other federal agencies and Ms. Denne answered that the laboratory collaborates with agencies such as the U.S. Geological Survey, the Department of Energy National Laboratories, the Bureau of Land Management, and NOAA. In reply to a question about a forensics group, she responded that EPA's National Enforcement Investigations Center often is referred to as the forensics group and mentioned that ESD's Environmental Chemistry Branch also does some forensics work.

## **Landscape Ecology Studies in the Western United States**

Dr. Heggem, Acting Branch Chief of the Landscape Ecology Branch, explained that landscape ecology is the linking of landscape pattern to an ecological process. He showed multi-spectral scanner images that depicted the landscape change in the Las Vegas Valley from 1972 to 2002. There has been substantial development of the Valley in that 30-year period. These studies, referred to as EMAP-West, are part of EPA's Environmental Monitoring and Assessment Program (EMAP) and the goals are to: (1) quantify

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relationships between landscape composition and pattern and measures of ecological/hydrological conditions; and (2) evaluated differences in results among different biophysical settings, scales, and measures of ecological/hydrological conditions. The purpose of EMAP-West is to demonstrate the value of the EMAP approach by applying it to environmental problems across a large and diverse geographic region, and to advance the science of ecosystem monitoring. This will be accomplished by applying EMAP designs to urgent and practical problems facing the western EPA regional offices.

Part of the effort involved an integrated risk assessment of the phosphorus in Oregon streams and rivers. The assessment indicated that phosphorus levels were high in areas dominated by agriculture. Ten percent of the stream length in Oregon has phosphorus concentrations exceeding the EPA criterion for flowing waters (0.1 mg/L).

Region 8 has indicated that the Landscape Ecology Branch (LEB) has been extremely supportive to the region in development of landscape indicators. In particular, the Analytical Tools Interface for Landscape Assessments (ATtILA) ArcView Extension tool and SEDMON/RUSLE2 Arc Macro Language scripts have been invaluable software. The Branch support on the development of grazing, nutrient, and sedimentation landscape indicators has been extremely useful. The LEB has been a strong partner to the region on both the development of landscape tools and indicators as well as the provider of landscape data.

The LEB has provided tribal assistance and technical support to Region 9. Specifically, the Branch helped assess changes to range land dynamics over a 30-year period on the South Fork Band of the Te-Moak Reservation. The LEB also helped assess changes to riparian vegetation and stream morphological structure in the Lower Truckee River on the Pyramid Lake Paiute Reservation, Nevada, over a 30-year period. The assessments addressed water quality, stream morphology, and aquatic community alterations, and source assessments associated with land use practices (e.g., increased sediment loads and inorganic contaminants). The LEB also provided training for tribal environmental programs in landscape ecology and spatial statistical analysis.

The LEB has provided tool development, data acquisition, and technical support to Region 10. The region has used ATtILA extensively in the development of total maximum daily load (TMDL) Source Assessments, along with regional western EMAP project reports. Region 10 receives support from NERL-Las Vegas on the application of the Soil and Landform Metric Tool, a GIS-based soil model for the EMAP-West project on the John Day Basin, Oregon. The laboratory has provided Region 10 many of the base GIS layers used in all subsequent EMAP-West analysis conducted by the region. Region 10 staff has been provided invaluable statistical support on the Regional Western EMAP project for Northwest Coast Range Ecoregion. Region 10 also was provided support on reclassification of the National Landcover Data Set (NLDC) for areas associated with harvest activities not included in the original classification. Through cooperation with NERL–Las Vegas on EMAP-West, Region 10 staff was provided access to training associated with the AGWA (Automated Geospatial Watershed Assessment) tool.

Dr. Heggem also described a scenario analysis for the San Pedro River that involved analyzing the hydrologic consequences of a future environment. The assessment included three base change scenarios: (1) constrained—assumes a population increase less than 2020 forecast (78,500) and development in existing areas (e.g., 90% urban); (2) plans—assumes a population increase as forecast for 2020 (95,000) and development in mostly existing areas (e.g., 80% urban and 15% suburban); and (3) open—assumes a population increase more than 2020 forecast (111,500), with most of the constraints on land development removed and development occurring mostly into rural areas (60%) and less in existing urban areas (15%). The 2000 baseline was compared with the three alternative future land cover/use scenarios. The key questions addressed were: What is the variance between the scenario that is most development/least conservation oriented, and the one that is least development/most conservation? Can growth patterns be managed to minimize hydrologic and environmental impacts? The assessment examined percent change

in surface runoff, channel discharge, sediment yield, and percolation between 2000 and 2020. The following conclusions were drawn from the assessment:

- ♦ All scenarios produce a generally negative set of impacts as a result of predicted urbanization.
- ♦ There is considerable variation—particularly between extremes produced by constrained and open scenarios.
- ♦ Groundwater recharge will decrease as impervious surfaces expand.
- ♦ Surface runoff will increase in all three scenarios.
- ♦ Sediment yield will increase as new surfaces are disturbed and increased surface runoff is available for transportation.
- ♦ There will be increased vulnerability of important riparian habitat and species as a result of changing hydrologic regime.

Dr. Windom asked if slope is considered in the models. He also asked about quality assurance. Dr. Heggem responded that slope is in the models and there is an individual devoted to spatial quality assurance. Dr. Demerjian asked if the laboratory interacts with the U.S. Forest Service (USFS). Dr. Heggem replied in the affirmative, stating that they have learned a lot from the lessons learned by USFS in using GIS to place equipment and crews to fight forest fires. Dr. Sayler asked if there was any collaboration with the CALFED San Joaquin River Basin Study. Dr. Heggem responded that there is some collaboration; that study is using the soil erosion maps generated by the program. Dr. Harding asked if the laboratory is sharing its information with EPA's Office of Water (OW), and Dr. Heggem answered that OW staff attended a week-long meeting at the laboratory in December 2005 to share information. Dr. Windom asked if the data are normalized for hydrologic conditions and suggested looking at baseflow conditions. Dr. Heggem responded that they are conducting monitoring work with the USGS to obtain data on baseflow conditions in the coastal region. They are finding that there are pulses with the seasons. Randy Wentsel (EPA/ORD) asked how the results of this research could be translated to the Eastern United States. Dr. Heggem replied that an ecoregion approach is essential.

## **Modeling of Human Exposures**

Dr. Dary, Chief of the Exposure & Dose Research Branch (EDRB) of NERL's Human Exposure & Atmospheric Sciences Division, stated that the Branch develops models and analytical tools to improve understanding of the relationships underlying human exposure to internal dose in an effort to reduce uncertainty in exposure and risk assessment to individuals and populations of concern. The objective is to develop exposure-dose modeling tools and analytical techniques to conduct research to help clients address priority Agency needs. The base program involves: (1) the development of exposure-dose models to characterize and assess human exposure, (2) use of a systems approach to characterize and quantify the exposures to individuals and populations, (3) evaluation and application of advanced computational techniques and emerging "omics" information and technologies to improve our modeling tools and methods, and (4) increased emphasis on integration and collaboration.

Dr. Dary identified some of the Human Exposure-Dose Modeling Program's current tasks and some of the recent accomplishments of the EDRB. These accomplishments include:

- ♦ Physiologically based pharmacokinetic (PBPK) modeling of trichloroethylene (TCE) and incorporation of that expertise in issue papers for the National Academies.
- ♦ Methyl tert-butyl ether (MTBE) modeling for risk assessment.
- ♦ N-methyl carbamate modeling, including evaluation against biomonitoring studies and cumulative model
- ♦ Malathion modeling of head lice treatments, including evaluation of labeled use.
- ❖ Pyrethroid cumulative risk assessment design to explicitly include PBPK/pharmacodynamic (PD) modeling.

♦ Exposure Related Dose Estimating Model (ERDEM) system development for use by other researchers, and complete communication of the models to the scientific community.

Some of the Branch's future focus areas are: (1) person/population oriented exposure modeling (occupational and incidental)—probabilistic stochastic and regulatory scenario-based assumptions; (2) uptake and dose modeling—ADME merging quantitative structure-activity relationships (QSAR) with PBPK and biomonitoring and dose reconstruction; and (3) pharmacodynamic modeling—target tissue and enzyme/receptor modeling and link with central dogma (genomics, proteomics, and metabonomics).

Dr. Dary identified a number of drivers/opportunities. There is an emerging Agency-wide interest in the application of PBPK/PD models for risk assessment, and human exposure modeling is required to meet Agency goals for quantitative assessment of cumulative risks from exposures to multiple compounds. Research in human exposure-dose modeling is required to inform public health decisions (interpretation of biomonitoring data, exposure classification for health studies, and exposure data and model predictions that feed into public health tracking platforms). Research also is required to develop tools for quantifying impacts of intervention and regulation.

There are a number of issues and challenges to address. Client needs for the program's products and technical expertise vary with exposure media, compounds, and exposure scenarios of interest. The level of technical expertise required to apply the models and interpret results varies with the science question and complexity of the model. Current and future demands for research in human exposure modeling are rapidly increasing. Integration and collaboration are required to address Agency needs.

With respect to cumulative risk assessment, the EDRB Human Exposure-Dose Modeling Program will: (1) develop computational tools to facilitate assessment and characterization of exposures resulting in cumulative risks, (2) develop approaches to address time-patterns of exposure, (3) develop approaches for incorporating mechanistic information on toxicity into dose models, and (4) apply models to assess vulnerable populations.

Cumulative risk is a consequence of aggregate exposure. Computational toxicology will improve links in the exposure-to-effect paradigm. Advanced computational toxicology and systems biology are being applied to link exposure to assess and predict risk. Quantitative risk assessment is enhanced through the application of computational chemistry, computational biology, and systems biology. Computational chemistry approaches can be applied to estimate model parameters. Systems approaches can be combined with computational chemistry tools to develop semi-quantitative methods for screening and prioritizing chemicals and exposures. Computational approaches for incorporating mechanistic information to address variability in exposure and dose models are being investigated.

Dr. Dary explained that exposure-dose modeling connects exposure with internal dose disposition through exposure-time histories that link xenobiotic uptake with PBPK/PD models. These models are, in turn, used to obtain mass balance equivalents of the parent xenobiotic and selected metabolites in tissue compartments. They also are used to calculate target tissue dose metrics for important toxicity endpoints while providing elimination profiles that can be tested against biomonitoring study data.

Models are important because they can be efficiently and effectively used to test regulatory assumptions prior to data acquisition so that field or laboratory study designs can focus in on data gaps. Models can be augmented to address regulatory changes while adhering to quality assurance requirements. Models can be used to predict target tissue dose metrics for toxicity endpoints of interest in humans for which testing is prohibited. Models also provide a structure to evaluate diverse sets of data.

There are a number of ways that models can improve exposure and risk assessment. Models are adaptable to the human situation where historical data are scarce and acquisition of future data is problematic. Models can be tested repeatedly as more and better data become available to arrive at a

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complete, representative, and reasonable portrait of risk. Models can be efficiently used for most any application with the understanding that the model structure conforms to good modeling practices.

Dr. Dary described some of the assays of the program. He stated that the Microtox assay is based on changes in observed luminescence of the test organism *Vibrio fischeri* due to exposure to toxic chemicals. The assay measures light output of the organism after exposure to the sample as compared to the control blank. A serial dilution is used to determine the EC<sub>50</sub> values. The IQ-Tox assay uses the test organism *Daphnia magna* and is based on the inhibition of galactose metabolism by various toxins. Metabolism is measured by cleavage of the pro-fluorescent galactose substrate resulting in the visible fluorescence throughout the transparent organism. Comparison of the Microtox and IQ-Tox assays showed significantly differing sensitivities with respect to various volatile hazardous compounds suggesting that both assays be used to determine the presence of unknown toxic vapors.

Computational chemistry has improved QSAR databases, (linear free energy relationships to determine solvation/partition chemical-specific parameters and classic force-field docking methods to determine metabolic parameters for P450's. These improvements are based on available and rigorous classical and quantum mechanical chemistry techniques.

Dr. Henderson stated that there is some concern about the validity of models. They need to be tested and the uncertainty documented. Also, there are some unknowns about applying the models to subpopulations. Dr. Dary comment that they begin with models based on data gleaned from the literature. They then incorporate the confidential business information data submitted to the Office of Prevention, Pesticides and Toxic Substances (OPPTS). For chlorpyrifos, the models were tested and uncertainty was analyzed. As more data are available the model is re-evaluated. This process yields very good prediction models.

Dr. Sayler asked about mixtures and multiple stressors. Dr. Dary responded that they plan to move toward synergism in the future. Dr. Sayler asked if the Office of Pesticide Programs (OPP) is the Branch's primary client and Dr. Dary replied that it is OPP and the registrant. Dr. Ryan asked about the availability and accessibility of these models. Are they going to be made accessible for the use of others? Dr. Dary responded that he preferred to restrict the use of these models so that EPA can provide oversight to ensure that the models are applied correctly.

Dr. Clark asked if the Branch has determined how it will interact with the NCCT. Dr. Dary replied that the Branch is working with the Center, and the area of emphasis is pharmacokinetics. They hope to incorporate pharmacokinetics in the assessment of pyrethroids. He noted that pharmacokinetics-based models deal with body burden rather than relative potency.

Dr. Giesy commented that the registrant must do modeling as part of the registration process. Do the registrants have access to these models? Dr. Dary replied that EPA has worked with some of the registrants to do the modeling. Dr. Giesy asked if EPA supplied the models with instructions and guidance and then both the registrant and EPA analyzed the results to develop a consensus. Dr. Dary confirmed that this was the process used, stating that it was very successful.

Dr. Demerjian commented that there are many complex modeling systems that have been made available to the research community. This is the best way to establish the credibility of these tools. Dr. Dary responded that ERDEM is on the Web and available to the public, but it should not be used for regulatory issues without appropriate expertise. He is concerned about misapplication of the models.

Dr. Lambert stated that pharmacokinetics is relatively straightforward most of the time but now it is possible to identify genes that increase susceptibility. Are these being plugged into the model? Dr. Dary said that they have incorporated cytochrome P450 into the model.

## **Tour of Sediment Sampler Device and Video**

The BOSC members viewed a video demonstrating the sediment sampler device developed by ESD. Members were able to examine the device and pose questions about its operation to NERL staff.

#### **Poster Session**

The following posters were available for review by the BOSC:

- 1. Characterization and Monitoring Branch Site Characterization Highway
- 2. Composite Sampling for Soil VOC Analysis
- 3. Screening for Toxic Industrial Chemicals Using Semipermeable Membrane Devices Interfaced with Rapid Toxicity Assays
- 4. Indirect Measurement of Biological Activity to Monitor Natural Attenuation
- 5. Re-evaluation of the Applicability of Agency Sample Holding Times
- 6. Unique Chemistry Solutions to Regional Issues
- 7. Putting Pollution on ICE: A New Tool for Environmental Forensics
- 8. Possible Ramifications of Higher Mercury Concentrations in Fillet Tissue of Skinnier Fish
- 9. Not All Forensics Are Created Equal: Measuring Chemical Species with Hyphenated Techniques
- 10. Environmental Photographic Interpretation Center (EPIC)
- 11. Remote Detection of Invasive and Opportunistic Plant Species in Great Lakes Coastal Wetlands
- 12. Satellite Imagery Analyses of the Mississippi River: A Map Series From Headwaters to the Gulf of Mexico
- 13. Macroinvertebrate Response to Land Use and Stream Chemistry in the Mid-Atlantic Coastal Plains
- 14. Utilizing Remote Sensed Land Cover to Determine Habitat Vulnerability in Wetlands
- 15. AGWA: Automated Geospatial Watershed Assessment Tool: A GIS-Based Hydrologic Modeling Tool
- 16. Southern Lake Michigan Beach Closures: Using Satellite Images to Identify Areas at Risk
- 17. Albemarle-Pimlico Basin
- 18. Neuse River Basin, NC: Virtual Field Reference Database
- 19. EPA Geospatial Quality Council: Promoting Quality Assurance in the Geospatial Community
- 20. Urinary Levels of 2,4-D and 3,5,6-Trichloro-2-Pyridinol for Spouses and Children of Pesticide Applicators in the Agricultural Health Study
- 21. Estimation of Chemical Specific Parameters within Physiologically Based Pharmacokinetic/Pharmacodynamic Models
- 22. Use of Exposure Related Dose Estimating Model (ERDEM) for Assessment of Aggregate Exposure of Infants and Children to N-Methylcarbamate Insecticides
- 23. Harmonization and Communication of PBPK Models Using the Exposure Related Dose Estimation Model (ERDEM) System: Trichloroethylene
- 24. Use of a Physiologically Based Pharmacokinetic Model to Estimate Absorbed Carbaryl Dose in Children After Turf Application
- 25. Suitability of Using *In Vitro* and Computationally Estimated Parameters in Simplified Pharmacokinetic Models
- 26. Kidney Toxicogenomics of Chronic Potassium Bromate Exposure in F344 Male Rats
- 27. Comprehensive PBPK Modeling Approach Using the Exposure Related Dose Estimated Model (ERDEM)
- 28. Evaluation of Multiple Pharmacokinetic Modeling Structures for Trichloroethylene
- 29. Use of Pharmacokinetic Models to Assess Occupational and Residential Pesticide Exposure
- 30. U.S. EPA's PM Supersites Program: A Major Successful Collaborative Air Quality Program Supporting States and Regional Organizations in Their Approaches to Reduce PM Levels in Air on Urban and Regional Scales

31. An Enzyme Linked Immunosorbent Assay (ELISA) Method for the Urinary Biomonitoring of Dichlorooxyacetic Acid (2,4-D).

## **Draft Charge for Standing Subcommittees Discussion (Continued)**

Dr. Henderson distributed a revised version of the draft generic charge for the standing subcommittees to the BOSC members for comment. This version reflects the comments during Thursday's discussion. Dr. Windom agreed with the changes and stated that the Laboratory/Center Directors must buy into it because the goal of these subcommittees is to assist the laboratories/centers. Dr. Giesy asked about items 3 through 8 from the previous draft and Dr. Henderson realized that she had inadvertently omitted the back page that contained those items. She agreed to revise those items in the next draft. Dr. Duke recommended removing the first one or two words of the items under the section entitled "Areas of Consultative Responsibility." For example, the words "Consultations of the" would be removed from item 1; the words "An assessment of the" would be removed from item 3; and the words "A review of" would be removed from items 4 through 8.

Dr. Giesy said that this charge should be examined in view of the BOSC's existing resources. He is concerned about creating four additional seven-member standing subcommittees. Dr. Demerjian suggested starting with three standing subcommittees and adding more over time. Dr. Demerjian asked if there could be one subcommittee for two laboratories (one for the National Risk Management Research Laboratory and NERL, for example). Ms. Kowalski noted that the laboratories are managed differently and in different geographic locations so it would be difficult to have one subcommittee for two laboratories. Dr. Demerjian asked if one subcommittee could handle the two subcommittees separately.

Dr. Windom stated that the BOSC has become much more productive in the past several years; the members have become more efficient and have been provided better tools (e.g., the Handbook). The BOSC needs to do some strategic planning to determine what it can do with the resources available. Dr. Henderson commented that the PART reviews were responsible for much of the BOSC's increased workload. She added that most of the members of the standing subcommittees would be non-Executive Committee members so she thought the workload would be manageable. Dr. Ryan said that he had volunteered to chair the NHEERL Standing Subcommittee but he would be willing to switch to the NRMRL Subcommittee if necessary.

Dr. Duke thought it might be helpful to get input from the laboratories/centers regarding which ones need help sooner than others. Dr. Henderson asked Ms. Kowalski to discuss this with Dr. Farland and the Laboratory/Center Directors as well as the revised generic charge. She asked Ms. Kowalski to express the Board's concern that the members may not be able to initiate four subcommittees at once. Ms. Kowalski agreed to raise these issues with Dr. Farland and the Laboratory/Center Directors. Dr. Giesy said that he is less concerned about the BOSC members' time and more concerned about EPA having the staff to support the subcommittees. Ms. Kowalski replied that she has worked out a staffing plan to support four standing subcommittees. She understands the workload and believes she has the resources to support the subcommittees. There is a tremendous amount of paperwork and there is a cost ceiling in the charter. She has estimated the cost and it will not be possible to support seven standing subcommittees this year. If they are phased in over time, EPA has the required resources. Ms. Kowalski is confident that EPA can support four new standing subcommittees (but no more than four given the other activities of the Board). She said that the BOSC also needs to discuss the process for mid-cycle reviews. She mentioned Dr. Farland's suggestion of linking these to Executive Committee meetings and doing two simultaneously.

Dr. Sayler asked how EPA plans to deal with conflicting advice. For example, the standing subcommittee could provide advice that conflicts with that provided in the program review. Ms. Kowalski responded that this is the major reason why the charge of the standing subcommittees has to be different from the charge for the program reviews. She added that FACA committees provide advice to EPA, not direction,

so conflicts are not critical. Dr. Giesy suggested adding a process for resolving conflicts in the handbook. There should be written procedures for the subcommittees to follow.

Dr. Lambert asked if the standing subcommittee meetings will be open to the public and Ms. Kowalski replied that they would be subject of all FACA requirements, including open meetings. She did not know whether consultations had to be open to the public, but she agreed to find out. Dr. Henderson thought that CASAC consultations were open to the public. Dr. Lambert suggested that workgroups may be more effective so that the consultations could be confidential. Dr. Windom asked for input from the Laboratory/Center Directors regarding what they expect to obtain from the subcommittees and if they think a public forum would hinder achieving their goals. He thought the current charge was too similar to that for the program reviews. Dr. Giesy asked if this was an appropriate task for the BOSC; perhaps the laboratories/centers should seek advice from a non-FACA source. Ms. Kowalski stated that the entire premise behind FACA is to open the meetings to the public. Workgroups are not subject to that requirement but all advice from a workgroup must go through the Executive Committee, which is subject to FACA. She noted that all of the Laboratory/Center Directors are aware of the FACA requirements and still support the concept of standing subcommittees. She agreed to ask Dr. Farland to raise this issue with them to confirm that they think that there will be value added with advice from a FACA committee.

Dr. Henderson asked if the BOSC members agreed that the draft charge, with the revisions suggested today, could be sent to Ms. Kowalski for distribution to the Laboratory/Center Directors. The members agreed that it should be sent to Ms. Kowalski. Ms. Kowalski will submit the revised charge to Dr. Farland and the Laboratory/Center Directors and obtain input regarding the charge, the effectiveness of FACA committees addressing their needs, and which laboratories/centers require advice first. Dr. Giesy suggested initiating two new standing subcommittees to work through the process and to develop a model for subsequent standing subcommittees.

## **Future BOSC Business**

Dr. Harding asked about the mid-cycle reviews. What will be involved in these reviews? Ms. Kowalski will send to the Board members a list of the program reviews that have been completed and the dates of the upcoming mid-cycle reviews. The list also will include the program reviews to be conducted. Perhaps Dr. Johnson will be able to work on a schedule for managing the workload.

Dr. Henderson asked about the next steps for the STAR/GRO Fellowship Program Review Report. The comments that were received could be incorporated by Dr. Duke and verified by the vettors. She asked if the members were ready to vote on approving the report. Dr. Sayler said he would prefer to see a revised report before taking a vote. Dr. Harding suggested that Dr. Duke review the list of comments drafted by the BOSC members as part of their homework last evening. Dr. Henderson asked Dr. Duke to incorporate the requested changes and prepare a revised report. Dr. Duke agreed to address the issues and revise the report. Ms. Kowalski will schedule a conference call, probably in July, to discuss the revised report and vote on its approval. She will send the members the revised report as soon as it is available.

Dr. Henderson indicated that the date for the October meeting needs to be changed. She asked the members to check their availability for the weeks of October 9, 16, and 23. Ms. Kowalski will send out an e-mail soliciting input on members' availability.

Dr. Henderson thanked the members for their efforts and adjourned the meeting at 12:27 p.m.

## **Action Items**

- ♦ Beverly Campbell will finalize the February 2006 BOSC Executive Committee Meeting Summary approved by the BOSC and submit it to Ms. Kowalski for posting on the BOSC Web Site.
- ♦ Ms. Kowalski will verify that members who received direct deposits under the old payroll system do not have to do anything to continue to receive direct deposits.
- ♦ Ms. Kowalski will send the BOSC members a follow-up e-mail about how to access the new payroll system. Board members will send her any questions they might have about the system and she will provide them the answers.
- ♦ Dr. Farland will provide the BOSC members the Web address for the strategy for sustainability research and the MYP on Technology for Sustainability so that they can review these two documents.
- ♦ Dr. Ryan agreed to serve as the Co-Chair of the Safe Pesticides/Safe Products Subcommittee.
- ❖ Dr. Harding will notify Ms. Kowalski which area(s) of expertise are filled by Dr. Ryan on the Safe Pesticides/Safe Products Subcommittee so that Ms. Kowalski can focus on the other areas.
- → The BOSC members will identify the areas of expertise that they would like to add to the Board when filling the remaining vacancies.
- ♦ The BOSC members will provide input on the approach to be used for the mid-cycle check-ins for the programs.
- ♦ Dr. Farland will make arrangements for a presentation to the BOSC by the Chair of the Human Studies Review Board at an upcoming Executive Committee meeting.
- ♦ Ms. Kowalski will send the BOSC Subcommittee members an e-mail notice to inform them that the ORD response to the report has been posted on the BOSC Web Site. The notice will provide the URL for the Web site.
- ♦ Ms. Kowalski will include some information on timing in the next revision of the handbook.
- ♦ Dr. Clark will provide his editorial comments on the handbook to Ms. Kowalski.
- ❖ Dr. Giesy will provide editorial comments on the draft generic charge for the standing subcommittees to Dr. Henderson.
- ❖ Dr. Demerjian volunteered to serve as the Chair of the NERL Standing Subcommittee unless the Agency considers that a conflict of interest. Ms. Kowalski will determine if there is any conflict of interest and notify the Board.
- ❖ Dr. Ryan agreed to serve as the Chair of the NHEERL Standing Subcommittee. If needed, he would be willing to Chair the NRMRL Standing Subcommittee instead.
- ❖ Dr. Giesy volunteered to serve as the Chair of the NCEA Standing Subcommittee unless, because he has a security clearance that could be activated, he should be the Chair of the NHSRC Standing Subcommittee.
- ❖ Dr. Henderson will ask Dr. Philbert if he would be willing to serve as the Chair of the NCEA Standing Subcommittee.

- ❖ Dr. Henderson will revise the draft generic charge for the standing laboratory/center subcommittees and send it to Ms. Kowalski.
- ♦ Ms. Kowalski will distribute the revised draft generic charge for the standing subcommittees to Dr. Farland and the Laboratory/Center Directors. She will ask Dr. Farland to obtain input from the Directors regarding the charge, the effectiveness of FACA committees in addressing their needs, and which laboratories/centers require advice first.
- ♦ Ms. Kowalski will determine if consultations of the standing subcommittees must be open to the public.
- ♦ Ms. Kowalski will send to the Board members a list of the program reviews that have been completed and the dates of the upcoming mid-cycle reviews. The list also will include the program reviews to be conducted. She will ask Dr. Johnson to consider developing a schedule for managing the workload.
- ❖ Dr. Duke will review the list of comments on the STAR/GRO Fellowship Subcommittee report drafted by the BOSC members at the meeting. He will incorporate the requested changes and prepare a revised report.
- ❖ Ms. Kowalski will schedule a conference call, probably in July, to discuss the revised STAR/GRO Fellowship Subcommittee report and vote on its approval. She will send the members the revised report as soon as it is available.
- ♦ Ms. Kowalski will send out an e-mail soliciting input on members' availability for the weeks of October 9, 16, and 23.

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# 32<sup>nd</sup> EXECUTIVE COMMITTEE FACE-TO-FACE MEETING AGENDA

## June 1-2, 2006

Monte Carlo Hotel and Casino 3770 Las Vegas Boulevard South Las Vegas, Nevada 89109 Tel: (702) 730-7777

## Thursday, June 1, 2006

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8:00 a.m. – 8:30 a.m.	Registration	
8:30 a.m. – 9:00 a.m.	Welcome and Introductions - New Member Welcome  - Review of Feb Mtg Minutes - Review of April Mtg Minutes - Reports Transmitted to ORD - SAB Budget Review - Overview of Agenda	Dr. Rogene Henderson, Vice Chair, Executive Committee
9:00 a.m. – 9:15 a.m.	BOSC DFO Remarks Office of - Administrative Issues	Ms. Lori Kowalski, Research and Development
9:15 a.m. – 9:45 a.m.	AA/ORD Remarks	Dr. George Gray, Administrator for Office of Research and Development
9:45 a.m. – 10:45 a.m.	Subcommittee Reports	
	<ul> <li>Science to Achieve Results (STAR)/ Greater Research Opportunities (GRO) Fellowship Program Review</li> <li>Chair Presentation of Draft Report</li> <li>Discussion</li> </ul>	Dr. Cliff Duke, Subcommittee Chair Executive Committee
10:45 a.m. – 11:00 a.m.	Break	
11:00 a.m. – 12:00 noon	Subcommittee Reports (Continued)	
	- Computational Toxicology	Dr. George Daston, Subcommittee Chair
	- Technology for Sustainability Program Review	Dr. John Giesy, Subcommittee Chair

	<ul> <li>- Human Health Risk Assessment Program Review</li> <li>- Safe Pesticides/Safe Products Program Review</li> <li>- Homeland Security</li> <li>- Program Review Tool Workgroup Status</li> </ul>	Dr. George Daston, Subcommittee Chair Dr. Anna Harding, Subcommittee Chair Dr. Gary Sayler, Subcommittee Chair Dr. Rogene Henderson, Vice Chair, Executive Committee
12:00 noon – 1:00 p.m.	Lunch	Committee
1:00 p.m. – 1:30 p.m.	BOSC Issues - ORD Update	Dr. William Farland, Acting Deputy for Science for Research and Development
1:30 p.m. – 2:15 p.m.	ORD Responses to Recent BOSC Reports	ORD Technical Leads
2:15 p.m. – 2:45 p.m.	BOSC Subcommittee Chair Handbook	Dr. Rogene Henderson, Vice Chair, Executive Committee
2:45 p.m. – 3:00 p.m.	Break	
3:00 p.m. – 4:00 p.m.	Implementing Standing BOSC Lab/Center Subcommittees	Dr. Rogene Henderson Vice Chair, Executive Committee
4:00 p.m. – 4:15 p.m.	Public Comment	
4:15 p.m. – 5:00 p.m.	Futures - Project Horizon Presentation	Ms. Anita Street, Office of Research and Development
5:00 p.m. – 5:30 p.m.	SAB Activities	Dr. George Lambert, SAB Liaison to the BOSC
5:30 p.m.	Adjournment	
Friday, June 2, 2006		
8:00 a.m. – 12:00 noon	Site Visit to National Exposure Research Lab (NERL) Facilities	Executive Committee Meeting Participants
12:00 noon – 12:30 p.m.	Future Discussion/Future Business - Meetings in 2006	Dr. Rogene Henderson, Vice Chair, Executive Committee
	- SAB Budget Review	Committee
12:30 p.m.	Adjournment	